

STRUT PERFORATION OF INFERIOR VENA CAVA FILTERS

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Abstract

This study aimed to determine and investigate the mechanical factors associated with the strut perforation of retrievable inferior vena cava filters (IVCFs) in patients. Furthermore, it aimed to reveal reasoning for the difference in perforation rates among male and female patients and between patients with and without a history of malignancy, as was observed in a former study. The resulting information could be used to discuss follow-up procedures and to determine if three-dimensional (3D) finite element modeling may be used to predict perforation. To perform this study, 37 patients indicating perforation with a Cook Celect IVCF were observed, each having at least three computed topography (CT) images after placement of the filter. Three-dimensional (3D) finite element modeling in ADINA was applied to simulate the IVCF at each CT image set. The 3D model was deformed according to the filter strut positions relative to the center of the filter calculated from the corresponding CT image. The resulting maximum and average total and normal forces on each strut face were recorded from the simulation and compared to the filter strut perforation in the following CT study. The percent of total perforated struts that occurred below a certain force value was plotted and a sigmoidal fit was determined. Additionally, the percentage of struts that perforated within a defined force range was calculated and plotted. The data was initially classified according to patient gender malignancy history. It was further classified according to IVC diameter at filter placement and in follow-up CT studies. By investigating the role of IVC diameter in combination with patient gender and malignancy history, it was observed that female patients and patients with a history of malignancy were more susceptible to perforation, particularly at lower IVC diameters. In patients with a history of malignancy, data suggested that lower forces can result in perforation. However, inconsistent results occurred for these forces in female patients. Further investigation may be required for a better understanding of the role of IVC diameters, in addition to patient gender and malignancy history. When observing patients with larger IVC diameters, the difference between female and male patients, and between patients with and without a history of malignancy, decreased.

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1. Introduction

When anticoagulation is not an option to treat a patient with venous thromboembolic disease, a permanent or retrievable inferior vena cava filter (IVCF) may be selected for use [1]. While both types of filters are approved for permanent use, the FDA has warned of complications arising from the long-term use of retrievable IVC filters [2]. Although safety concerns exist, follow-up recommendations are lacking and IVCFs often not removed, leading to strut perforation among other complications. Interestingly, one study has noted that strut perforation is the strongest predictor of complicated filter retrieval procedures [3]. Therefore, a goal of this study was to assist in the development of follow-up procedures to prevent unnecessary retrieval complications by studying a Celect IVCF (Cook Medical, Inc.). To reach this goal, the mechanical factors related to perforation, a significant retrieval complication, was studied. This was accomplished by implementing a 3D finite element model in the ADINA 8.9 finite element package (Adina R&D, Inc., Watertown, MA) to study the progression of mechanical aspects of the filter over the course of its perforation in CT studies after filter placement. Additionally, this study investigated whether the employment of finite element modeling, in conjunction with CT studies, can aid in revealing the risk of strut perforation in patients. Lastly, it aimed to reveal reasoning for the difference in perforation rates among male and female patients and between patients with and without a history of malignancy, as was observed in a former study.

2. Background

In the FDA's warning, a number of life-threatening complications resulting from the long-term use of retrievable IVCs are listed, including concerns of mechanical failure, filter movement, strut perforation, and the challenge of removing IVCs [2]. Despite these risks associated with long-term use of IVCs, retrievable IVCs are often not assessed or removed following insertion. Rates of removal for retrievable IVCs differ among studies, ranging from 3.7% to 58.9% [4, 5]. It should be noted, however, that these rates are reported with varying timespans after placement.

With low retrieval rates, filters remain in patients for extended periods of time, which has been shown to increase the rate and degree of perforation. In one such case, strut perforation was discovered in all patients that had a CT scan at least 71 days after placement [6]. Also, this study evaluated CT images for up to 880 days after placement and, as expected, resulted in higher perforation rates (78%-93%) than in other studies. In comparison, a study with an average of 355 days until a CT study after placement indicated a 56% perforation rate, lower than the previously mentioned study [7]. Moreover, the percentage of patients followed after IVC placement is low. In a study of 272 filters, 19% had an available CT study within 880 days following placement [6].

In addition to higher perforation rates over time, the retrieval failure rate increases with time after placement. Success rates fall from 94% within 12 weeks to as low as 67% at 26 weeks, depending on the filter brand [8]. This decreasing success rate has been linked to the increased percentage of patients with strut perforation, which complicates the retrieval procedure. Furthermore, the strongest predictor of complicated filter retrieval has been found to be filter strut perforation [3]. This may suggest that complicated retrieval rates can be reduced by determining patients at risk for perforation through follow-up care.

With a goal to develop follow-up recommendations and assist in the prevention of complicated retrievals, a previous study had been performed on the Celect IVCF at The Ohio State University to determine at risk populations for perforation and the mechanical factors



Figure 1: Celect IVCF [9]

associated with perforation [10]. This study indicated an increased percentage of strut perforation over time, from 36% at a 75 day average to 71% at a 316 day average. Overall, 66% of 91 patients showed progressive perforation. From this study, it was determined that female patients were significantly more susceptible to perforation than male patients. Additionally, patients with a history of malignancy showed an increased percentage of perforation. In addition, the study indicated that the initial perforation results in a decrease of the IVC diameter, and therefore increasing the potential for additional perforation.

To study the mechanical factors of perforation, a 3D finite element model was developed and imported into the ADINA 8.9 finite element package. By developing this 3D finite element

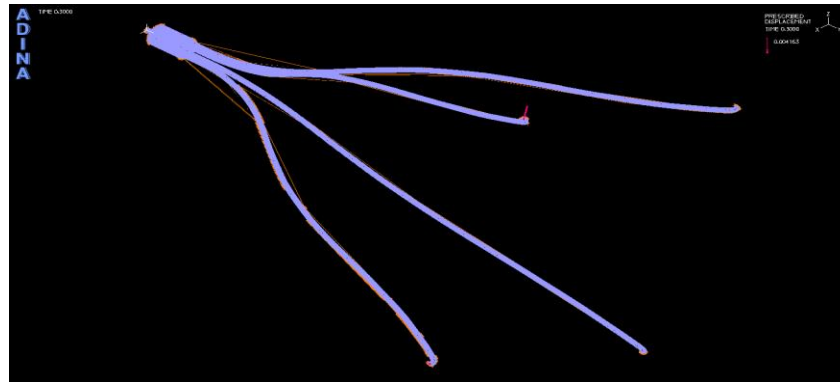


Figure 2: ADINA model of Celest IVCF

model of the IVCF, the strut forces acting on the walls of the IVC were measured while varying IVC geometry, either circle or elliptical, and size, either diameter or aspect ratio. This revealed that both normal and shear forces are present on the strut faces and increased with a larger displacement, which affects strut perforation.

Furthermore, this previous study deformed the 3D finite element model to match the placement of the filter in seven patients with perforation. In this small group size, it indicated that the strut carrying the higher normal and total force was more likely to perforate before the next CT study. Additionally, perforations occurred at lower forces for patients with malignancy. The purpose of this study was to expand the previous study by further implementing the finite element model for patients indicating strut perforation and to determine if finite element modeling may be used to reveal a risk of perforation. Lastly, it was to more comprehensively study and determine the mechanical factors of strut perforation and a reason for the difference in perforation rates among the previously studied populations.

3. Research Methodology

3.1 Patients

The study included 37 patients from the previous study's population that showed perforation [10]. Each patient had an infrarenal Cook Celect IVCF placed between May 1, 2008 and September 4, 2010. Additionally, all patients had at least three follow-up abdominal CT studies. The patients included in this study had an average age of 58.81 years with a total of 21 men, 16 women, and 26 having a history of malignancy.

3.2 Imaging

CT studies showing the entire IVC filter for the included patients were previously obtained in the initial study by searching the institution's picture archiving and communication system (PACS) (Agfa, Mortsel, Belgium) [10]. For patients with more than three CT studies, the earliest study, the latest study, and the median study between initial and final dates were observed, resulting in a total of 111 CT studies for the 37 evaluated patients.

Review of each CT study was completed in the previous study to determine primary and secondary IVC strut perforation. Strut perforation was defined as a strut greater than 3 mm outside the IVC wall, in agreement with the Society of Interventional Radiology practice guidelines [11].

3.3 Computer Modeling

A 3D model of the Celect IVCF was developed in ADINA in the previous study and was again implemented in this study to evaluate the IVCF in each CT study [10]. The model consisted of the center clamp ring connected to the four primary struts with a diameter of 0.42 mm. The Celect IVCF consists of the material Conichrome and was modeled with a Young's modulus of 200 GPA and a Poisson ratio of 0.23 [12, 13].

In order to apply the model to the IVCF in the CT studies, ImageJ [14] was applied to measure the location of the filter. The center of the filter clamp and the center of each primary strut face were measured. The positions of the primary strut faces were then calculated relative to the center of the filter clamp. These positions were then related to the un-stressed filter shape in order to calculate the displacement boundary conditions to be applied at the center of each primary strut face. Additionally, a fixed boundary condition was applied to the clamp ring of the filter in the translational x, y, and z directions and the rotational x and z directions. Rotation was allowed around the long axis, or y-axis, of the filter as this was observed in vivo from the previous study. The resulting maximum and average total and normal forces on the primary strut faces were recorded for each model. The two average forces are the forces experienced by the IVC wall. This process was repeated for each CT study for the 38 observed patients.

4. Results

4.1 Patient Statistics

Based on the previous study's review of the CT studies, the strut perforation rate of the 37 patients observed in this study was calculated to characterize the sample population. All 37 patients included in the study indicated perforation of at least one strut among the three CT studies. The first CT study occurred at a mean of 55 days after filter placement. At this time point, 4 (11%) patients showed perforation of one primary strut. Therefore, 2.7% (4/148) of primary struts had perforated by the first CT study. At the second follow-up CT study with a mean of 337 days after placement, 33 (89%) patients showed perforation. At this time point, 50% (74/148) of primary struts were perforated. Lastly, at the final CT study at a mean of 599 days after placement, all patients and 64% (94/148) of primary struts indicated perforation. This is summarized in Table 1 on the next page. Additionally, Table 2 contains the characteristics of all 91 patients evaluated in the previous study to indicate the sample of 37 patients is similar to that of the total 91 patients.

Table 1: Evaluated patient characteristics

	Number of Patients	Mean Age at Filter Placement (years)	Patients with Perforation (%)			Mean Days Between CT Studies			Mean IVC Diameter (cm)			
			First CT	Second CT	Third CT	Filter Placement to First CT Study	First to Second	Second to Third	At Filter Placement	First CT	Second CT	Third CT
Overall	37	58.81	11	89	100	55	282	262	2.12	1.96	1.88	1.80
Malignancy	26	61.27	15	88	100	64	286	269	2.13	1.96	1.87	1.79
No Malignancy	11	53.00	0	64	100	32	273	244	2.09	1.96	1.90	1.84
Female	16	58.25	6	88	100	28	232	251	2.07	1.93	1.96	1.84
Male	21	59.24	14	90	100	75	320	270	2.16	1.98	1.81	1.77
Progressive	11	62.55	36	100	100	109	264	261	2.15	1.98	1.94	1.91
Non-progressive	26	57.23	0	85	100	32	290	262	2.10	1.95	1.85	1.76

Table 2: Total patient characteristics

	Number of Patients	Mean Age at Filter Placement (years)	Patients with Perforation (%)			Mean Days Between CT Studies			Mean IVC Diameter (cm)			
			First CT	Second CT	Third CT	Filter Placement to First CT Study	First to Second	Second to Third	At Filter Placement	First CT	Second CT	Third CT
Overall	91	58.20	36	71	76	75	241	216	1.98	1.92	1.87	1.81
Malignancy	65	62.88	45	77	82	72	264	236	2.00	1.91	1.87	1.79
No Malignancy	26	51.50	15	58	62	86	184	168	1.93	1.94	1.86	1.86
Female	47	57.02	45	82	84	76	247	207	1.98	1.75	1.78	1.70
Male	44	58.43	28	62	68	69	220	212	1.99	1.97	1.83	1.80
Progressive	30	63.20	77	100	100	92	274	251	2.03	1.88	1.92	1.84
Non-progressive	61	57.87	16	57	64	67	225	199	1.96	1.94	1.84	1.80

Progressive perforation, or additional perforations occurring after initial perforation, occurred in 30% (11/37) of patients. This progressive perforation can be observed in the increase of perforated struts at the following CT study in these 11 patients, as noted in Table 1. At the initial CT study, 9% (4/44) primary struts perforated. This increased to 41% (18/44) at the second CT study and to 70 % (31/44) at the final CT study. However, in patients without progressive perforation, the percentage of perforated struts showed significantly less of an increase between the second and third CT studies as expected. At the initial study, 0% (0/104) of primary struts perforated. This increased to 59% (61/104) at the second CT study and slightly raised to 61% (63/104), a significantly smaller increase than was seen in progressive perforation. Interestingly, the mean number of days to the first CT study varied greatly between patients with and without progressive perforation. For patients with progressive perforation, the first CT study occurred at a mean of 109 days after placement, greater than the mean of 32 days for the patients without progressive perforation. This difference may indicate that the first CT study in patients without progressive perforation occurred too early to capture an initial perforation before the second CT study.

Based on the results of the previous study that indicated perforation was more likely to occur in patients with a history of malignancy than those without, the percentage of total struts perforated in both groups were calculated. Patients with a history of malignancy showed a higher percentage of struts perforated, in comparison to non-malignancy, at all three CT studies, 4% (4/104), 55% (57/104), and 66% (69/104), respectively. Percentages for non-malignancy were 0% (0/44), 48% (21/44), and 57% (25/44), respectively. It should be noted, however, that CT studies occurred at a greater mean number of days after placement for malignant patients, as seen in Table 1.

Additionally, the percentage of perforated struts was calculated based on patient gender due to the previous study's observation that perforation was more likely to occur in female patients. These results are shown in Table 1. Female patients showed a slightly lower percentage of struts perforated in comparison to male patients at all three CT studies. However, the mean days between filter placement and the three CT studies were greater for male patients, which may allow for more perforations to be observed. At the first CT study, the mean days after placement were 28 and 75, respectively for female and male patients. A greater difference was observed for the second CT study of 232 and 320 mean days, respectively, after the first CT study, respectively. The third CT study continued this trend with 251 and 270 mean days, respectively, after the second CT study. This significant increase in mean days may have allowed for perforations to be observed in male patients over time than in female patients.

4.2 Computational Models

4.2.1 Overall

To build upon the previous study and determine if higher strut forces result in strut perforation, the ADINA model of the Celect IVCF was deformed according to the CT images for each patient. Additionally, this would indicate if simulation of the IVCF in CT studies could reveal a risk of strut perforation. Simulations for all three CT studies were performed for each patient, resulting in three total IVCF models per patient. A strut force was considered to cause perforation if the strut perforated at the following time point. Strut forces at the third CT study were not included as a force that caused or did not cause perforation since there was no following CT study to compare. The number perforated struts that perforated below a certain average total strut force value was recorded and the percentage of total perforated struts was calculated as a function of the force value based on the following equation.

$$\text{Percent of Total Perforated Struts below } F_i = \frac{\text{Number of Strut Perforations Occuring Below } F_i}{\text{Total Number of Perforated Struts}} \quad (1)$$

This percentage was then plotted against the average total force of the strut and is shown below in Figure 3.

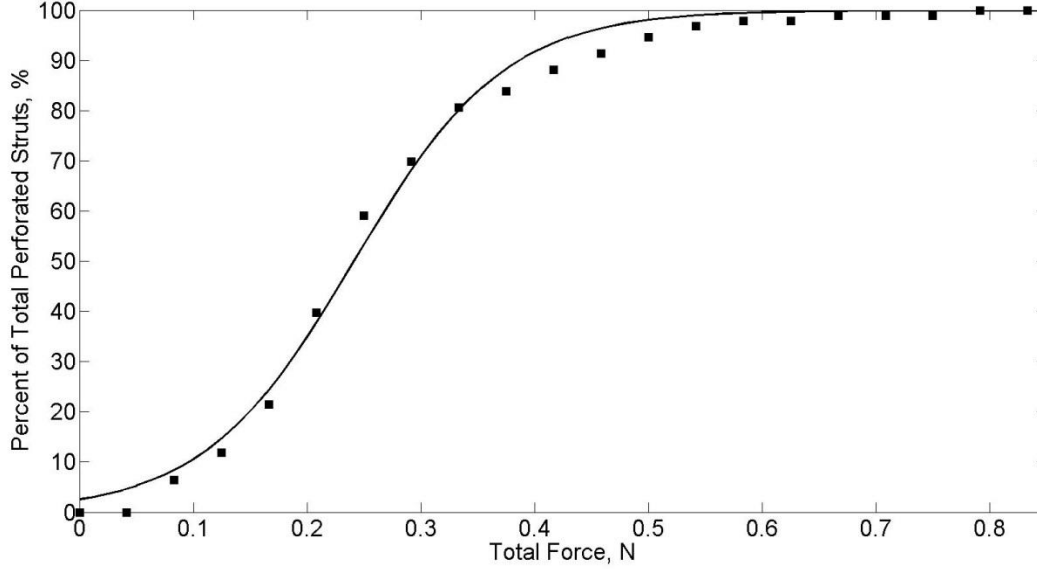


Figure 3: Percent of struts resulting from average total force below a specific value for all patients

The graph indicates that higher forces on the strut faces are more likely to result in perforation in comparison to lower forces. The data was fit to the sigmoidal function shown below:

$$P(F) = \frac{100\%}{1 + e^{-\left(\frac{F - F_0}{b}\right)}} \quad (2)$$

where F_0 is the force at the inflection point and b is the steepness of the curve at the inflection point. The values for the two variables are shown below in Table 3.

Table 3: Values from sigmoidal fit for all patients

F_0	b	F_{25}	F_{75}
0.2413	0.0661	0.1687	0.3139

Additionally in this table are the average force values for 25% and 75% strut perforation, 0.1687 and 0.3139 N, the boundaries for a force range that correspond to the middle 50% of strut perforation.

In order to include forces that did not cause perforation into the analysis, a second method of plotting the data was implemented. This was accomplished by determining the percentage of struts that perforated within a defined force range, as seen in the below equation:

$$\text{Percent of Perforated Struts between } F_i \text{ and } F_{i+1} = \frac{\text{Number of Strut Perforations Occuring between } F_i \text{ and } F_{i+1}}{\text{Total Number of Struts with a Force between } F_i \text{ and } F_{i+1}} \quad (3)$$

The resulting graph for all patients is shown below. It should be noted, however, that at a limited

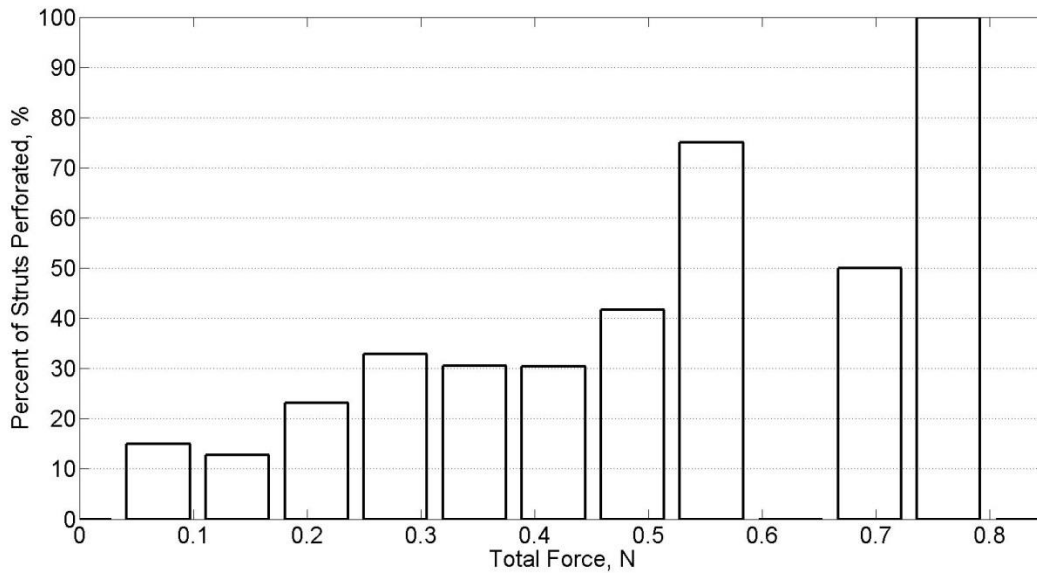


Figure 4: Percent of struts perforating in a defined force range

number of struts had forces greater than 0.6 N. Therefore, percentages in this range may be inaccurate. As expected, the percentage of perforated struts increased with increasing average total force.

4.2.2 Patient Gender

Based upon results of the previous study that indicated female patients are more susceptible to perforation, the patients were grouped according to gender. The perforation forces

were then plotted in the same method using equation 1 in order to provide a comparison of the forces that cause perforation based on gender.

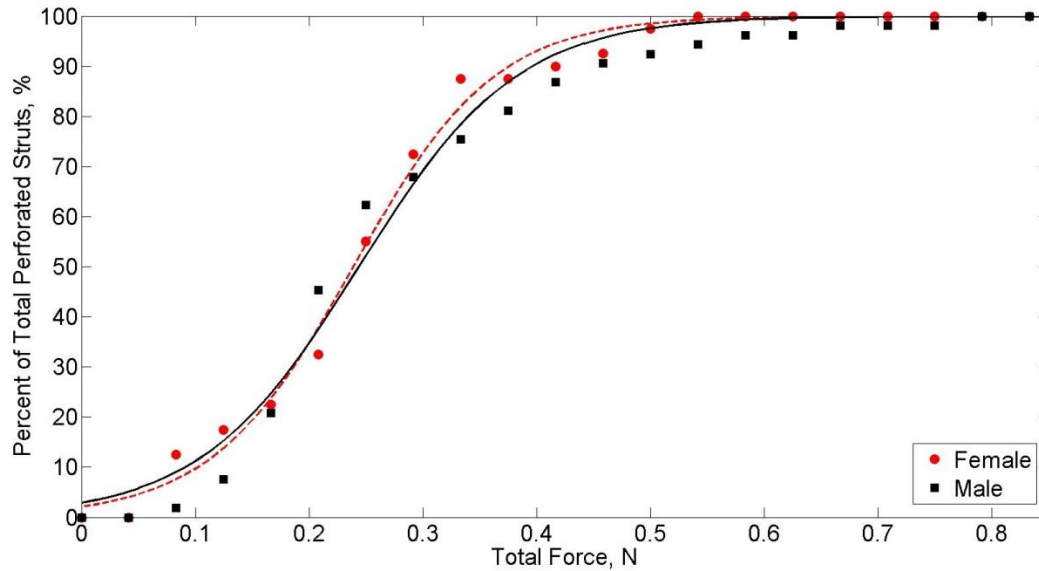


Figure 5: Female and male patients

As seen in the above plot, there was little difference in the distribution of forces that cause perforation between female and male patients. A lack of difference was confirmed by a two-sample t -test ($p = 0.4615$), and the mean difference with a 95% confidence interval (CI) is shown below.

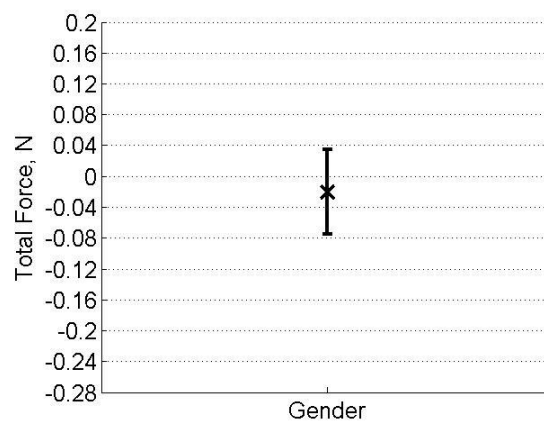


Figure 6: Mean difference of forces causing perforation in female and male patients

This was consistent with the previous study. The two sets of data were again fit to the sigmoidal function in equation 2 and the calculated values are shown in Figure 7. It should be noted, however, that grouping by gender is reevaluated with increased specifications in following sections.

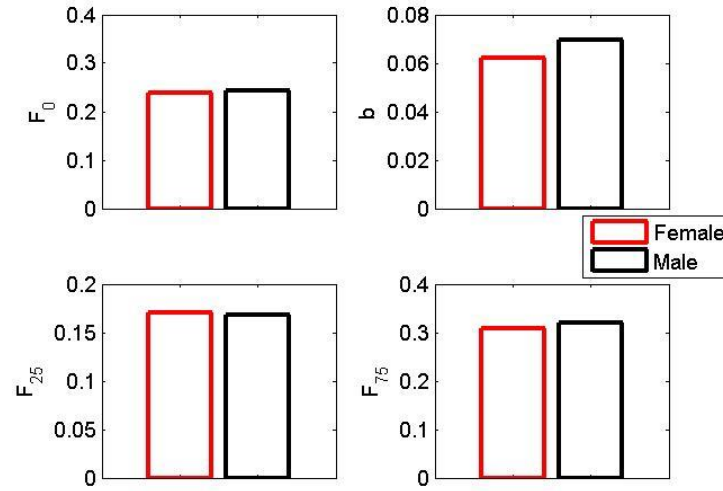


Figure 7: Female and male patient sigmoidal fit values

Additionally, the plotting method including forces that did not result in perforation was repeated for these two patient groups. In the majority of force ranges, female patients indicated a higher perforation percentage in comparison to male patients, as seen in Figure 8.

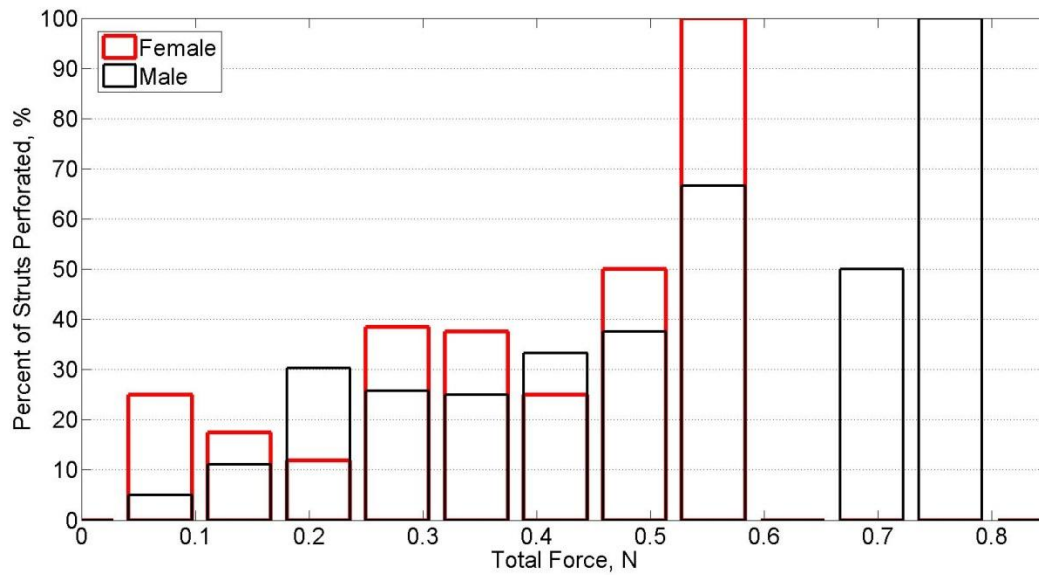


Figure 8: Percent of struts perforated in a force range for female and male patients

4.2.3 Patient Malignancy History

In the previous study, a significant difference in forces that cause perforation for patients with and without a history of malignancy was observed. To further support this finding, the 37 evaluated patients were grouped according to malignancy history.

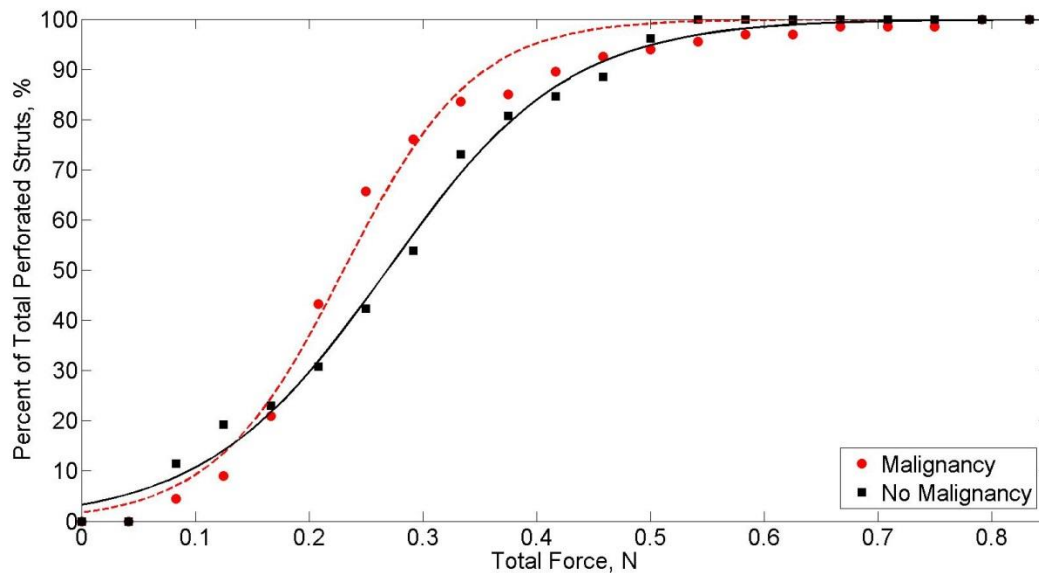


Figure 9: Patients with and without a history of malignancy

On the previous page, a difference is visible between the two curves, but not to the degree found in the previous study. Furthermore, the mean difference of the force data for the two groups was insignificant ($p = 0.5324$) and is shown below using a 95% CI.

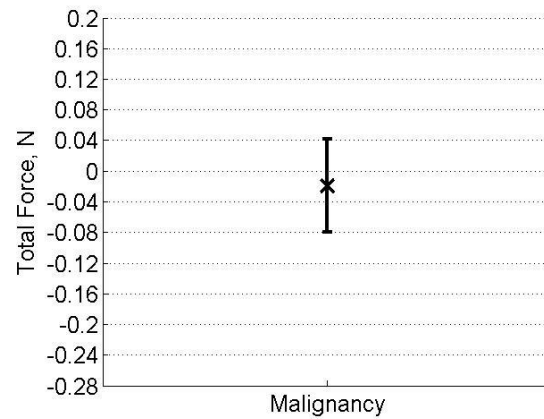


Figure 10: Mean difference of forces causing perforation in patients with and without a history of malignancy

The sigmoidal fit values for this grouping are shown below in Figure 11. These values indicate a greater difference between the two groups in comparison to the grouping by patient gender.

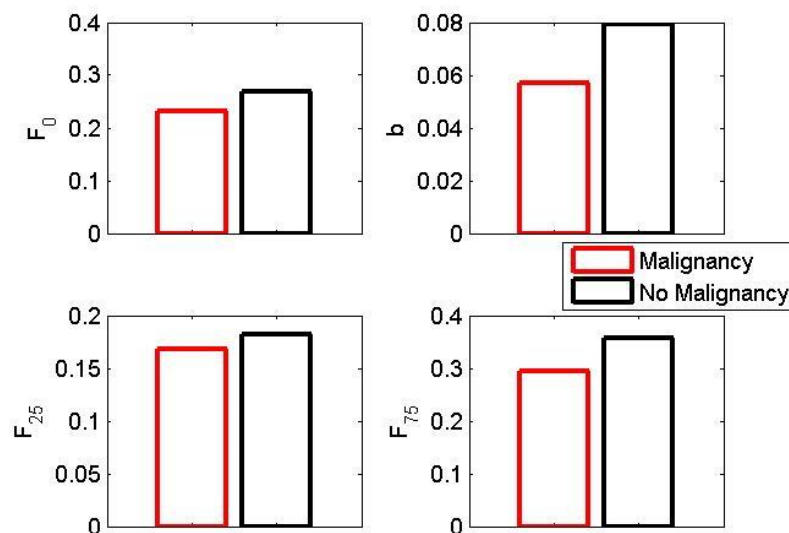


Figure 11: Sigmoidal fit values for malignancy grouping

When replotting the data using the second method, less of a difference was seen between the two patient groups. Unlike the same plot comparing female and male patients, there

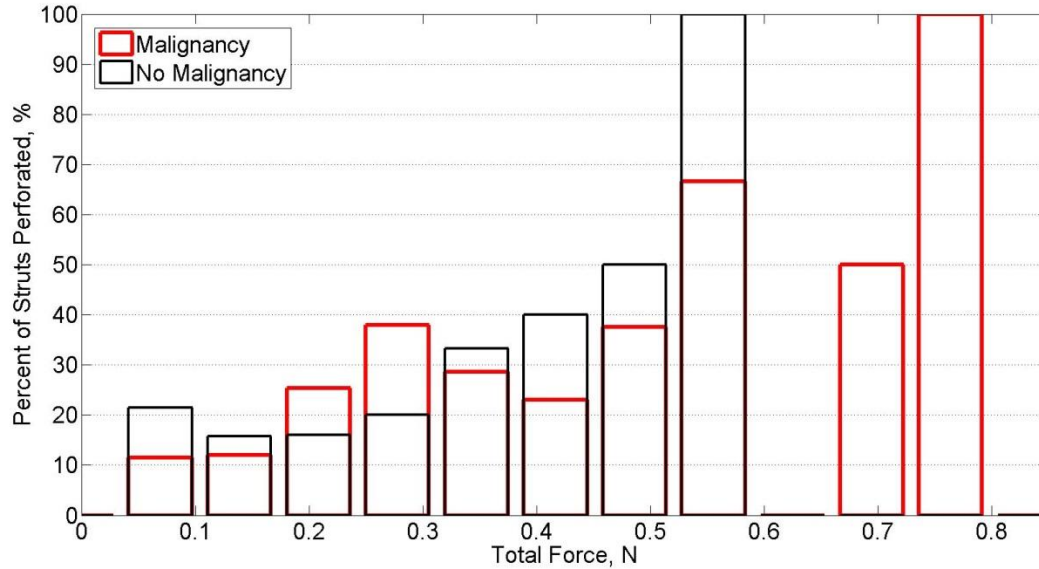


Figure 12: Patients with and without a history of malignancy

was less of difference in this plot compared to the sigmoidal curves.

Therefore, grouping all patients by gender and by malignancy provided no explanation for the significant difference in perforation rates between females and males, and between patients with and without a history of malignancy.

4.2.4 Days between CT Studies

Without a difference of perforation forces among the groups of patients, the data was further analyzed. It had been noted earlier that the mean number of days between CT studies for the observed patient groups varied, particularly for the male and female patient grouping. To determine if there was a connection among the days between CT studies and the observed perforations, the force data was plotted against the number of days between CT studies. Additionally, it was indicated on the plot whether the force resulted in perforation in the following CT study.

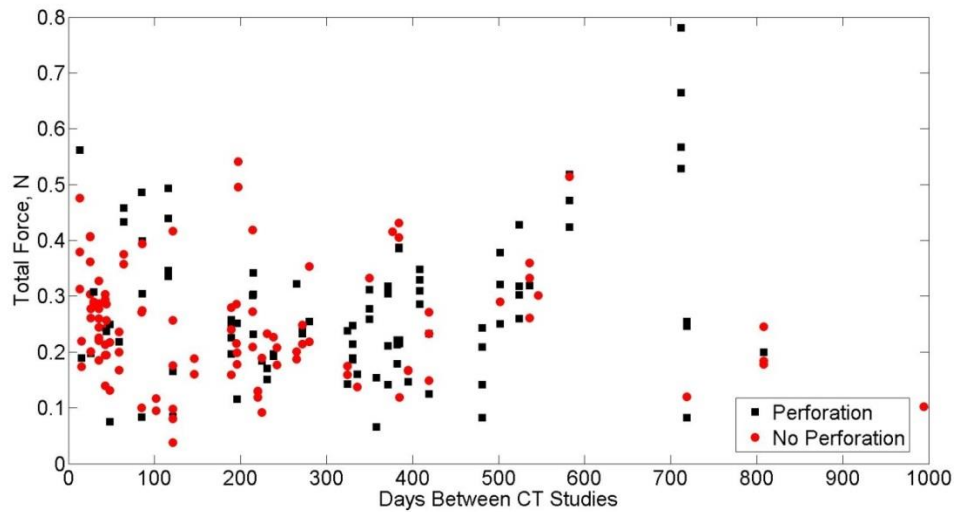


Figure 13: Average total force values based on perforation result and days between CT studies

Interestingly, a significant portion of forces that were calculated and then compared at a CT study less than 50 days later did not result in perforation. This may suggest that the timespan of about 50 days is often too short to allow perforation to occur. Based on this observation, the data was again sorted by patient gender and malignancy history but the days between CT studies were specified to be greater than 50 days. The resulting plot for male and female patients is shown.

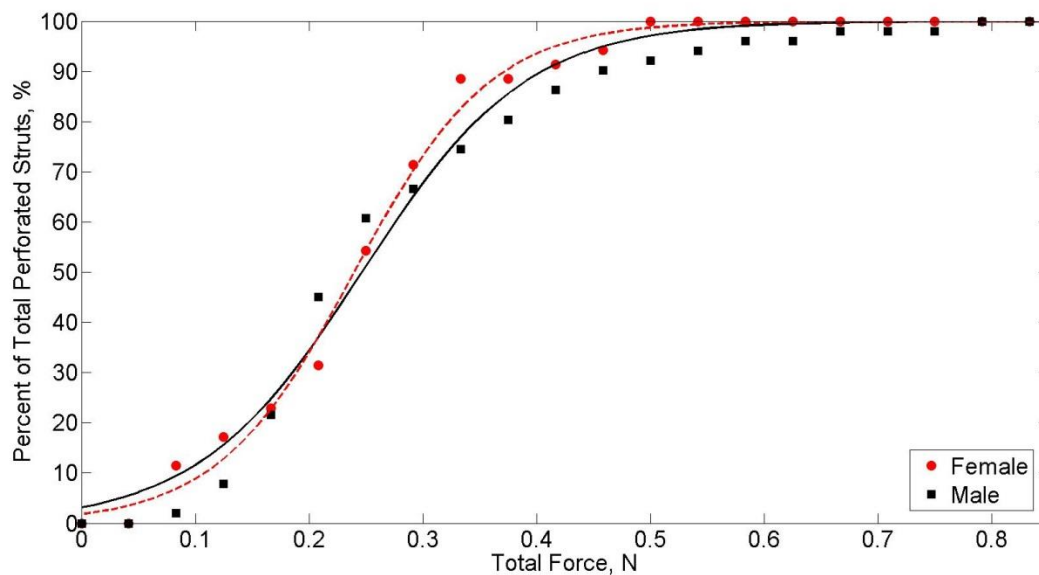


Figure 14: Female and male patients for CT studies greater than 50 days apart

Despite male patients having a significantly larger mean number of days between CT studies than female patients, the plot did not deviate from the results in Figure 5. Again, the mean difference was insignificant ($p = 0.3835$), as seen below.

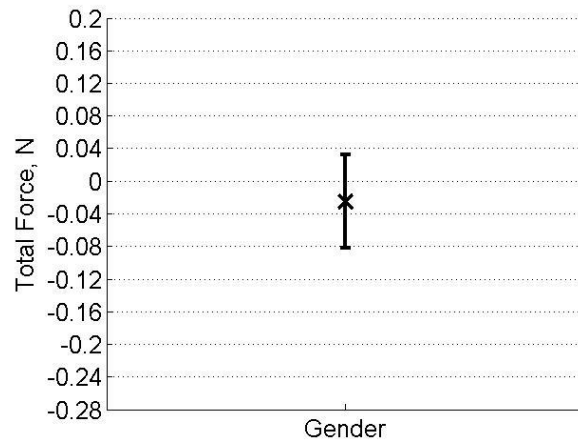


Figure 15: Mean difference for gender groups for CT studies greater than 50 days apart

The plot for patients based on malignancy history was also replotted, as seen in Figure 16, by filtering out the CT studies that occurred less than 50 days apart.

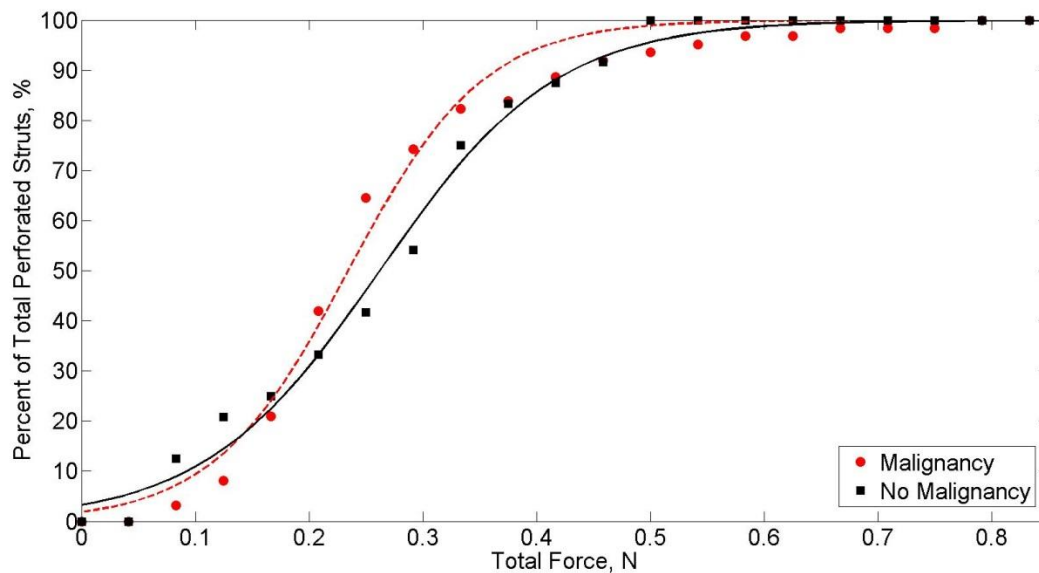


Figure 16: Malignancy groups for CT studies greater than 50 days apart

Again, removing force values for the specified day range resulted in no increase in difference between the malignant and non-malignant curves, and appeared to slightly reduce the difference found previously in Figure 9. Additionally, t -test results indicated no significant difference ($p = 0.8864$) among the two groups.

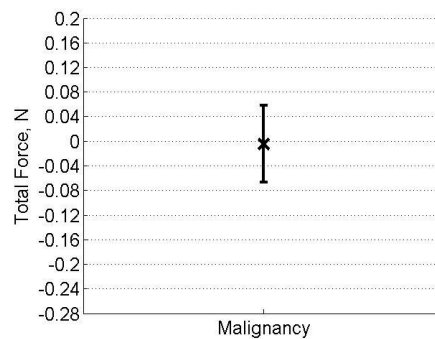


Figure 17: Mean difference for malignancy groups for CT studies greater than 50 days apart

The lack of change in the previous two plots may be explained based on how the plotted data was calculated. It was calculated using only forces that caused perforation, and therefore excluding data that largely did not cause perforations would have a minor impact. However when defining a lower range of 50 to 300 days between CT scans, the resulting plot in Figure 18 indicated perforations occur at lower forces in patients with a history of malignancy.

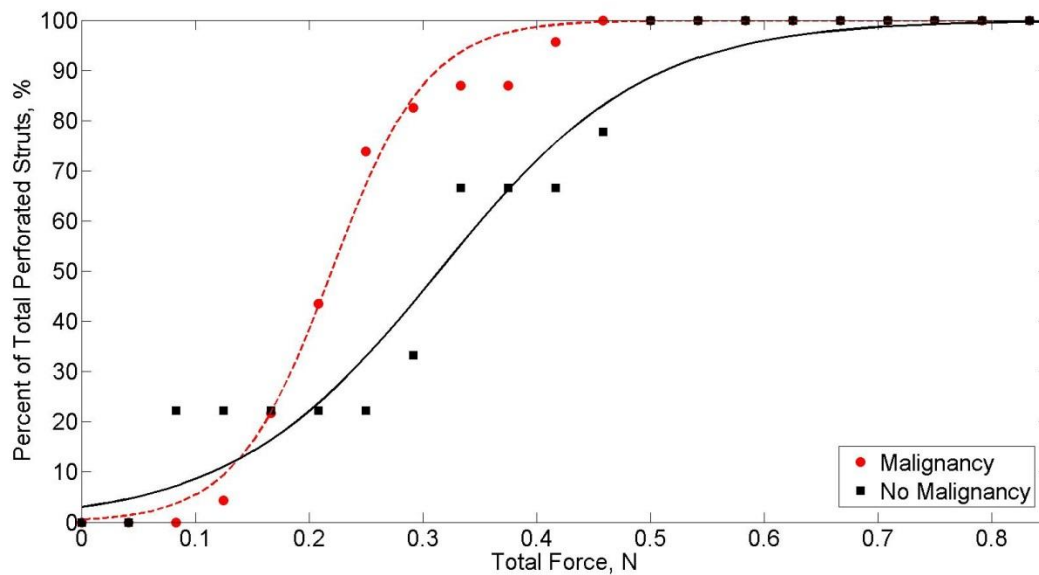


Figure 18: Malignancy groups for CT studies between 50 and 300 days apart

However, this day range limited the number of data points and the sets of forces were not statistically significant ($p = 0.1115$).

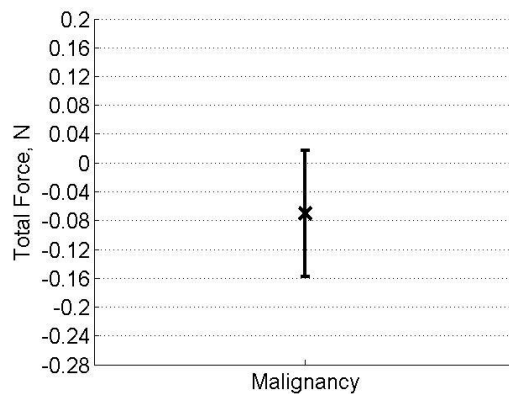


Figure 19: Mean difference for malignancy groups for CT studies between 50 and 300 days

The effect on defining the range of days between CT studies for plotting was also studied for a range between 50 and 600 days. This showed no difference from previous to plots for days over 50. Furthermore, the range of days was varied but no results provided an increase in difference among the curves for either grouping. Furthermore, no additional effect was observed when applying a range of days to plots including forces that did not result in perforation.

4.2.5 Inferior Vena Cava Diameter

Next, the effect of the inferior vena cava diameter on forces that result in perforation was investigated. This was considered based on the idea that if the difference in perforation rates between genders and malignancy histories is at least partially a result of different IVC wall properties, this effect would be less pronounced at larger IVC diameters as strut force is expected to decrease with less deformation. Below is a plot of force values that resulted in perforation and did not result in perforation against IVC diameter.

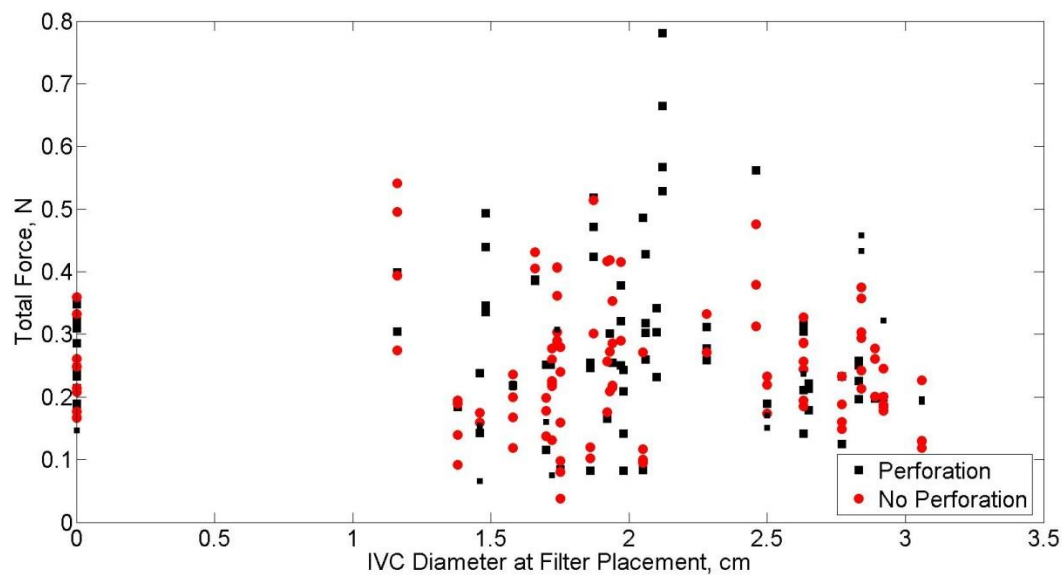


Figure 20: Perforation forces based on IVC diameter at filter placement

Unlike the plot based on days between CT studies, there was no observable trend in the plot based on the IVC diameter at filter placement. It should be noted that the data points located at 0 cm correspond to the four patients whose initial IVC diameter was not recorded.

When including a specified IVC diameter at filter placement range, the plot for female and male patients indicated a noticeable change in perforation forces. More specifically, this occurred when specifying a range of diameters as 1.3 to 2.3 cm, corresponding to the mean IVC

diameter within one standard deviation found in other studies [15]. The male and female patient groups were replotted in Figure 21 for this IVC diameter range.

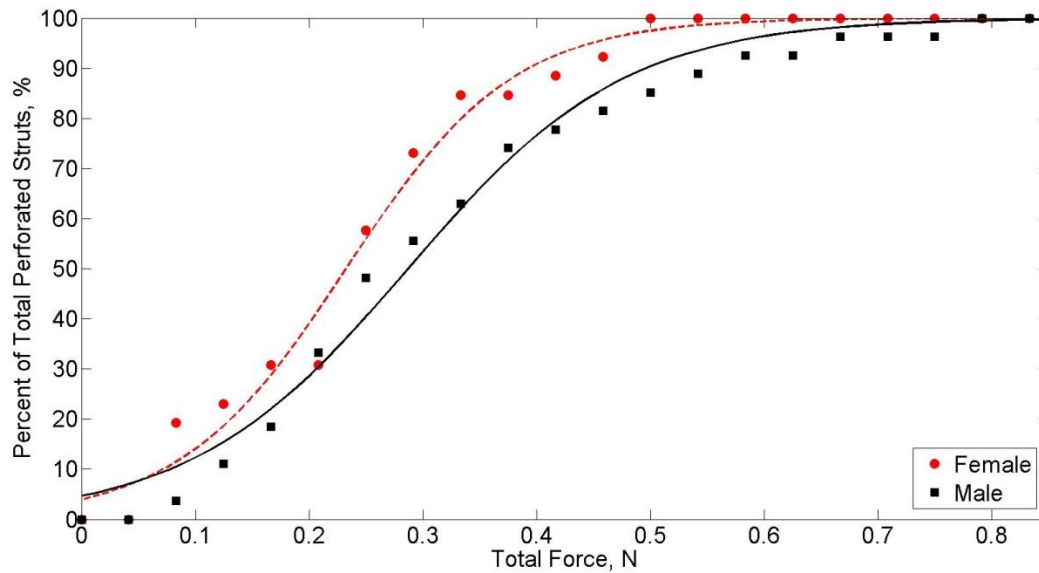


Figure 21: Female and male patients with an IVC diameter between 1.3 and 2.3 cm at filter placement

By including only male and female patients within a normal IVC diameter range, a difference in the forces that cause perforation was observed, and was significant at a 0.1 level ($p = 0.811$).

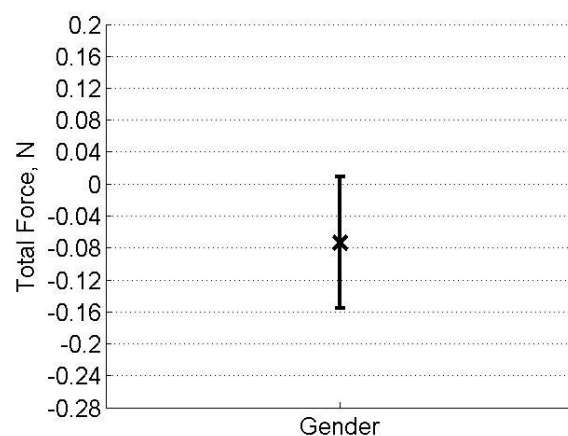


Figure 22: Mean difference in gender groups with an IVC diameter between 1.3 and 2.3 cm at filter placement

Next, this IVC diameter range was applied to patients grouped based on malignancy history, as shown in Figure 23.

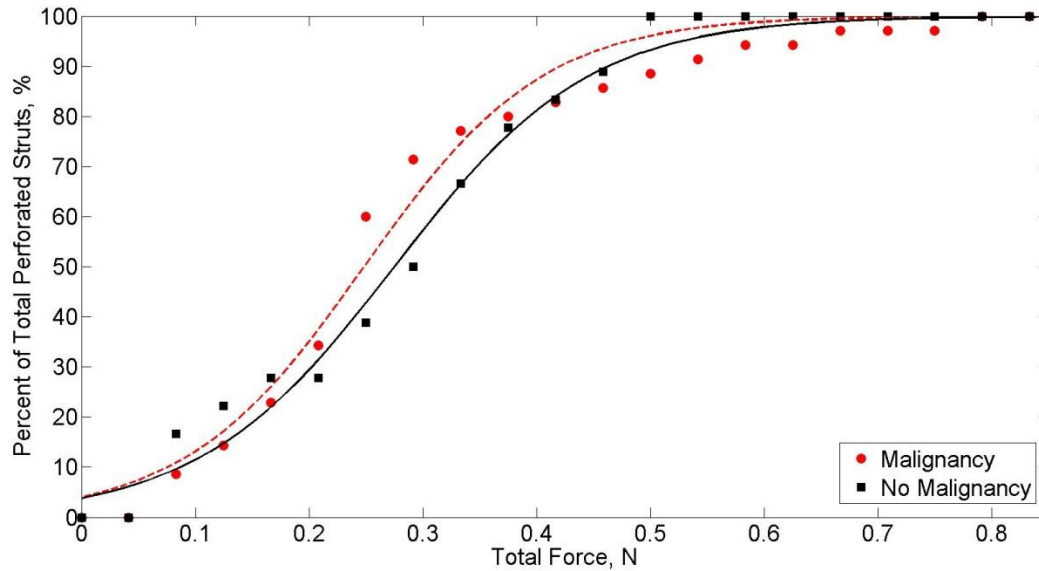


Figure 23: Malignancy history groups with an IVC diameter between 1.3 and 2.3 cm at filter placement

Although applying an IVC diameter range showed greater difference between gender groups, it resulted in less of a difference for the malignant grouping, as seen below. This was an

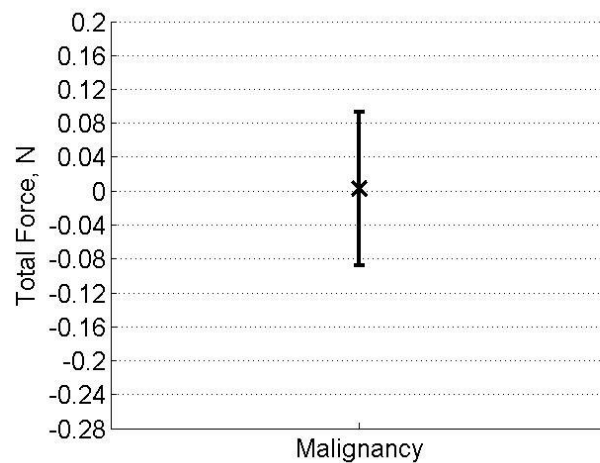


Figure 24: Mean difference for malignancy history groups with an IVC diameter between 1.3 and 2.3 cm at filter placement

insignificant difference ($p = 0.9528$).

With these differing results, the impact of IVC diameter at filter placement was further investigated. This process was reported for diameter ranges of 1 to 2 cm, 1.5 to 2.5 cm, 2 to 3 cm, and 2.5 to 3.5 cm. Interestingly, when the IVC diameter at filter placement range was adjusted, an overall trend for both patient groupings was observed. At an IVC diameter range of 1 cm near the mean IVC diameter based on other studies, such as 1.5-2.5 cm, the difference in patient groups was more pronounced. When lowering this range to 1-2 cm, the difference was still observable but not as obvious. Adjusting the range to higher values, such as 2-3 cm and 2.5-3.5 cm ranges, removed the differences previously seen between the patient groups. Despite the patient grouping based on malignancy history initially indicating a difference without an IVC diameter range, an IVC diameter range greater than the mean removed the difference. These plots can be seen in Appendix A. Additionally, plots including forces that did not cause perforation for the IVC diameter at filter placement ranges are located in Appendix A. These plots did not indicate any significant differences when the IVC range was applied.

To further study the effect of IVC diameter on perforation forces, the IVC diameter at a specific CT study was used to test the above ranges. This was considered based on the previous study's finding that IVC diameter decreased following strut perforation. In Table 1, the evaluated patients showed a mean decrease of 0.32 cm in IVC diameter from filter placement to the final CT study. Furthermore, it was expected that using IVC diameters at the CT study where the forces were calculated would provide a more accurate representation. It is observed in the plot

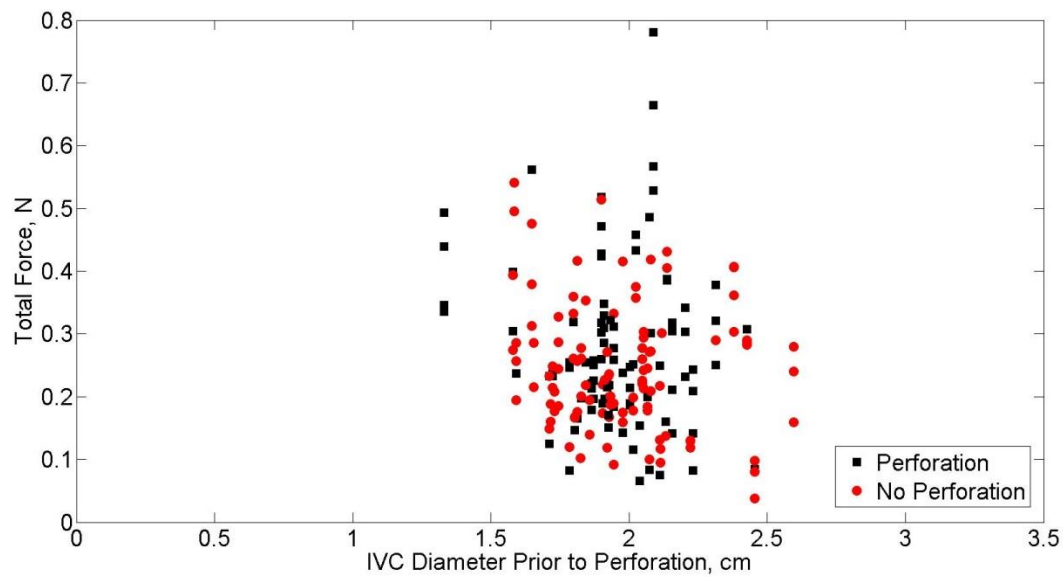


Figure 25: The IVC diameter and force combination for a given perforation used the IVC diameter at the CT study preceding perforation

that IVC diameters decreased in comparison to the previous plot of IVC diameters. This new plot is shown above in Figure 25. As a result, the IVC diameter range of 2.5 to 3.5 cm was not tested.

When evaluating patients within the 1.3 to 2.3 cm IVC diameter range, the difference between genders was eliminated while the difference between malignancy histories increased in comparison to using the IVC diameter at filter placement. However, when applying an IVC diameter range of 2 to 3 cm, above the normal range, a significant difference was observed between male and female patients, as shown below.

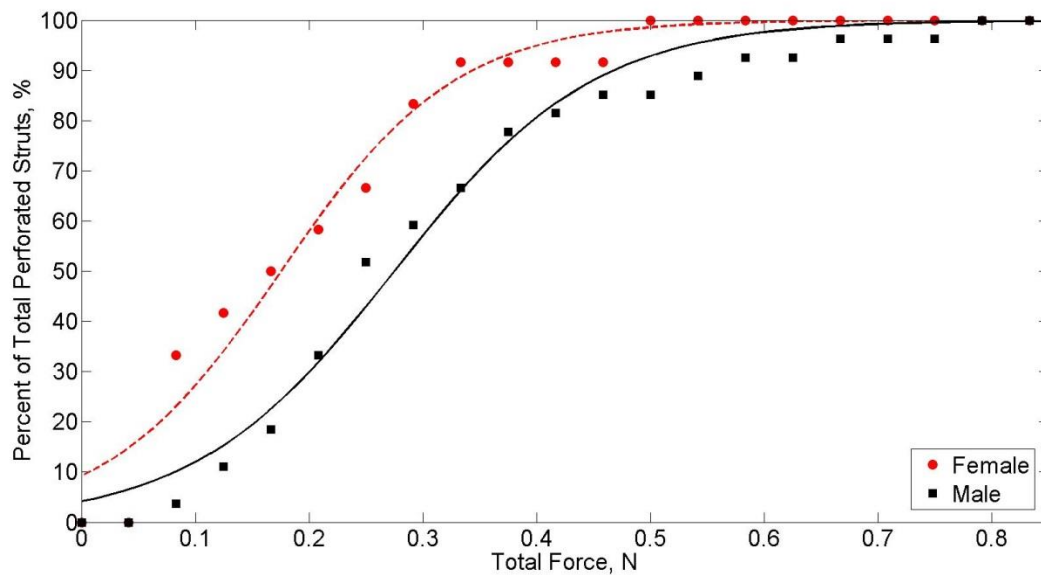


Figure 26: Female and male patients with an IVC diameter between 2 and 3 cm before a given perforation

These data sets were significant at a 0.1 significance level ($p = 0.0506$), suggesting that the

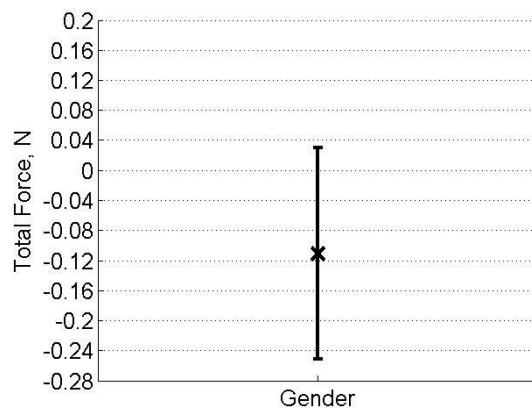


Figure 27: Mean difference for female and male patients with an IVC diameter between 2 and 3 cm before a given perforation

different perforation rates for female and male patients may result from some effect at larger IVC diameters. The values obtained from the sigmoidal fit, along with those for other IVC ranges, are shown in Figure 28. By adjusting the range to, 1 to 2 cm, the reverse occurred: perforations in

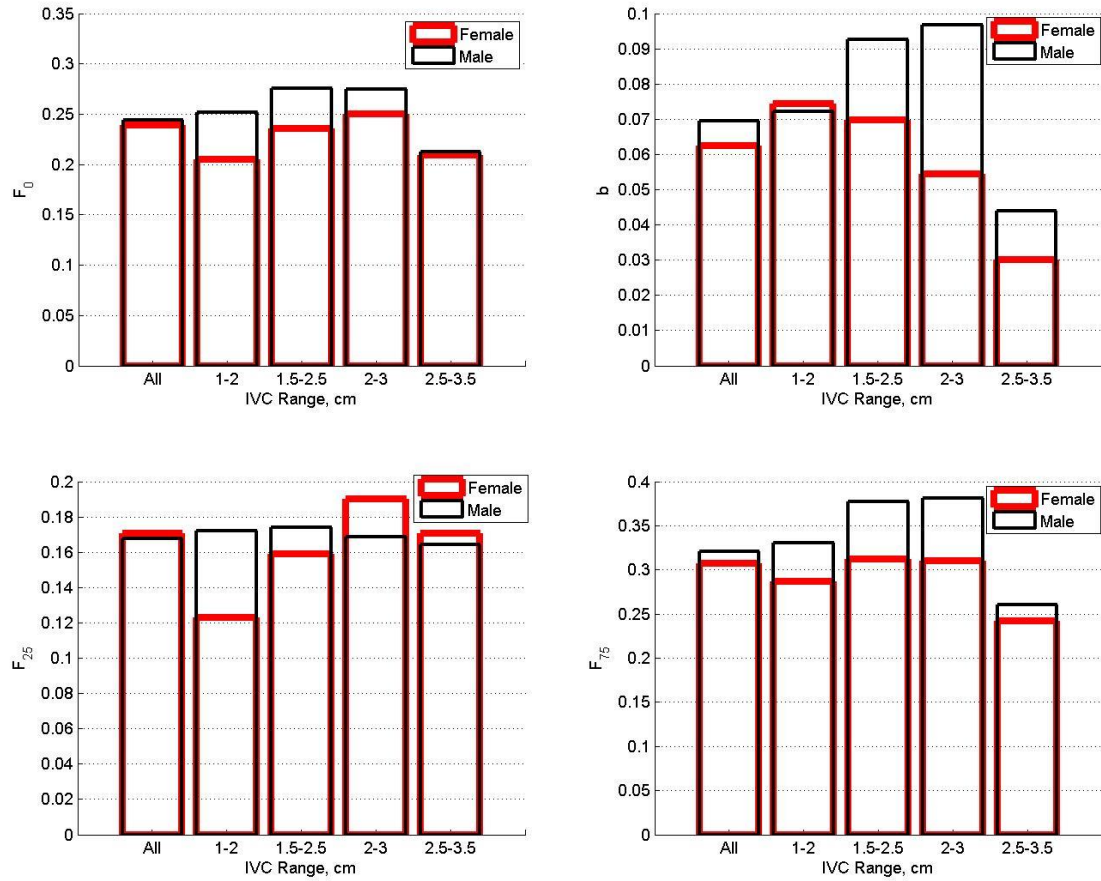


Figure 28: Sigmoidal fit values for female and male patients with different IVC diameter ranges

male patients occurred at lower forces. The plots for the other IVC ranges for female and male patients are located in Appendix A.

However, this finding in the sigmoidal plot was contradicted when including forces that did not result in perforation. The below figure shows the four graphs that correspond to three ranges for an IVC diameter prior to a given perforation, along with a plot including all IVC diameters. In the 1 to 2 cm range, female patients indicated a higher percentage of struts

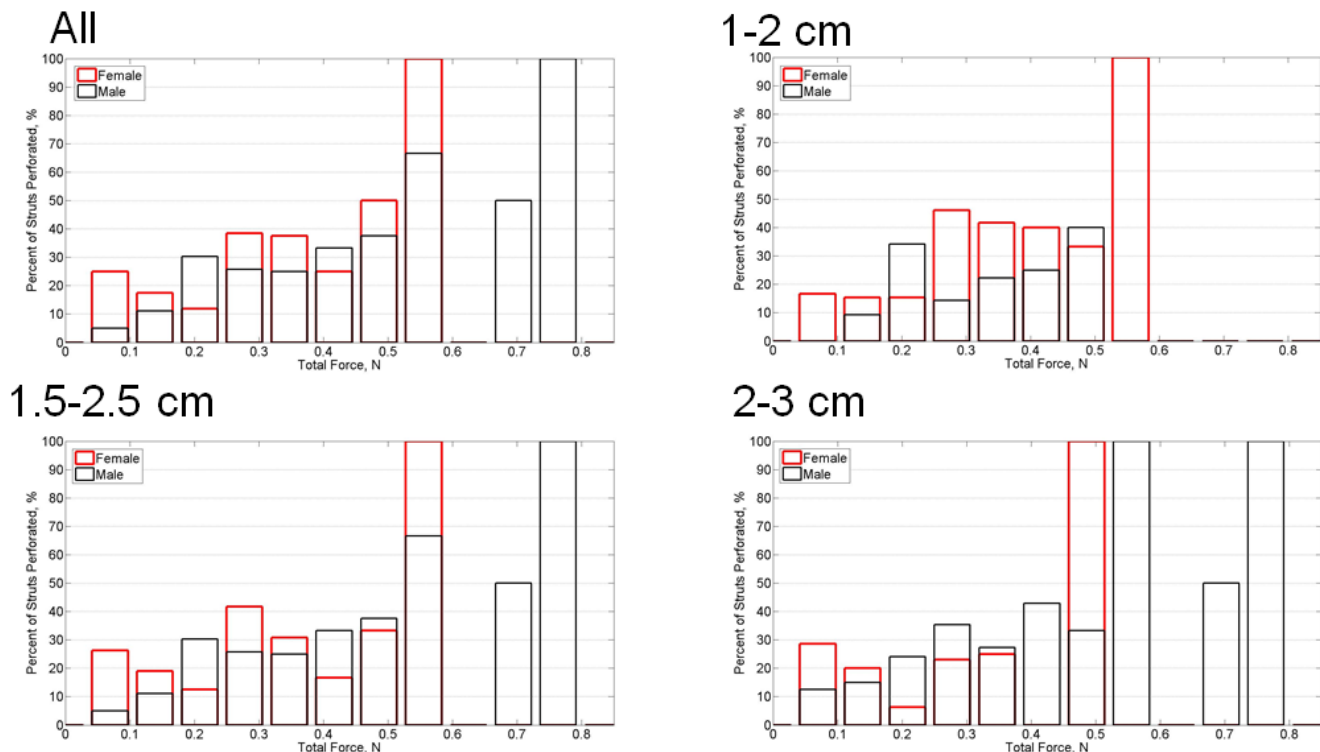


Figure 29: Percentage of struts that perforated in a given force range for ranges of IVC diameter prior to the given perforation

perforated in comparison to male patients. However, when increasing the IVC diameter range, this difference decreased. Unlike the sigmoidal plot, this trend suggests that female patients with low IVC diameters are more susceptible to perforation.

This process was then applied to patients with and without a history of malignancy. Interestingly, the opposite effect was seen in comparison to the male and female patients. With an IVC diameter range of 1 to 2 cm, perforations in patients with a history of malignancy occurred at significantly lower forces.

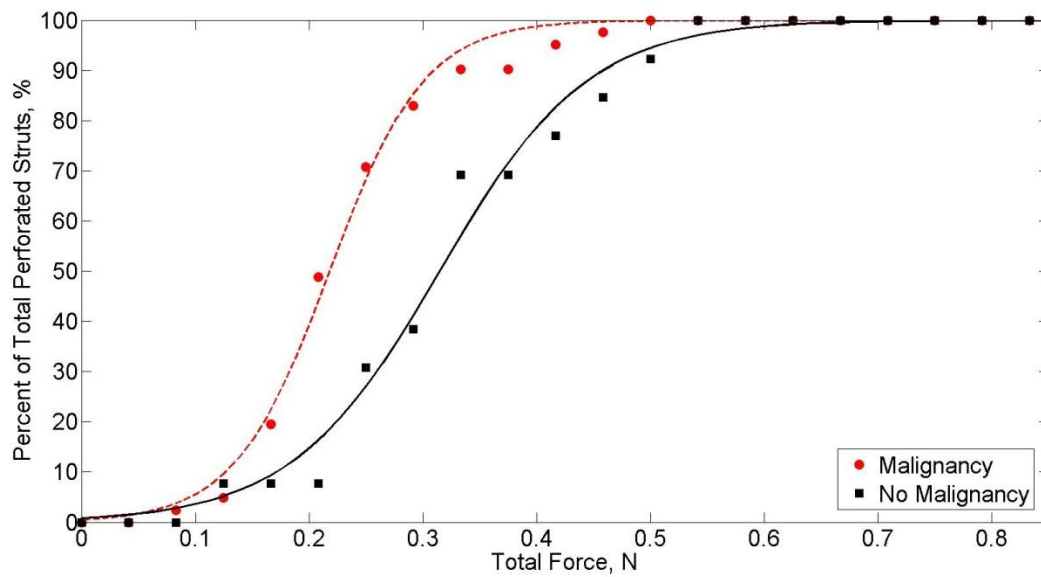


Figure 30: Patients with and without a history of malignancy with an IVC diameter between 1 and 2 cm before a given perforation

Below is the mean difference of the two force sets, indicating a significant difference at this IVC range ($p = 0.0044$).

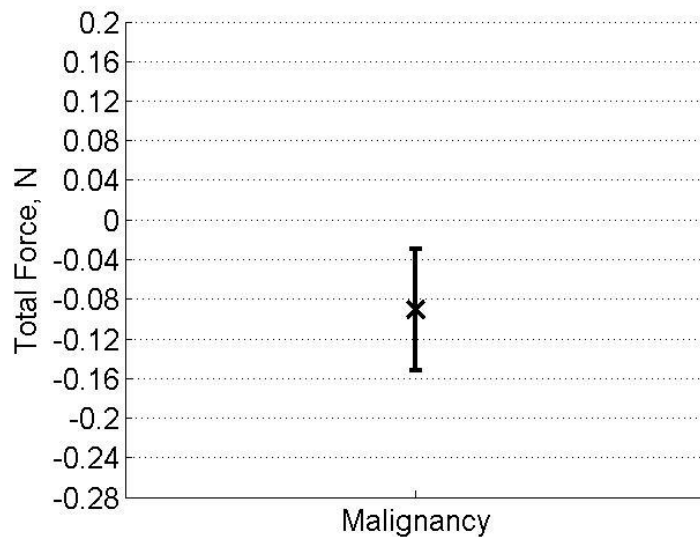


Figure 31: Mean difference for patients with and without a history of malignancy with an IVC diameter between 1 and 2 cm before a given perforation

Additionally, at ranges for IVC diameters between 2 and 3 cm, perforations occurred at lower forces in patients without a history of malignancy, as shown in Appendix A. Sigmoidal fit values for the different IVC ranges for patients with and without a history of malignancy are shown below in Figure 32.

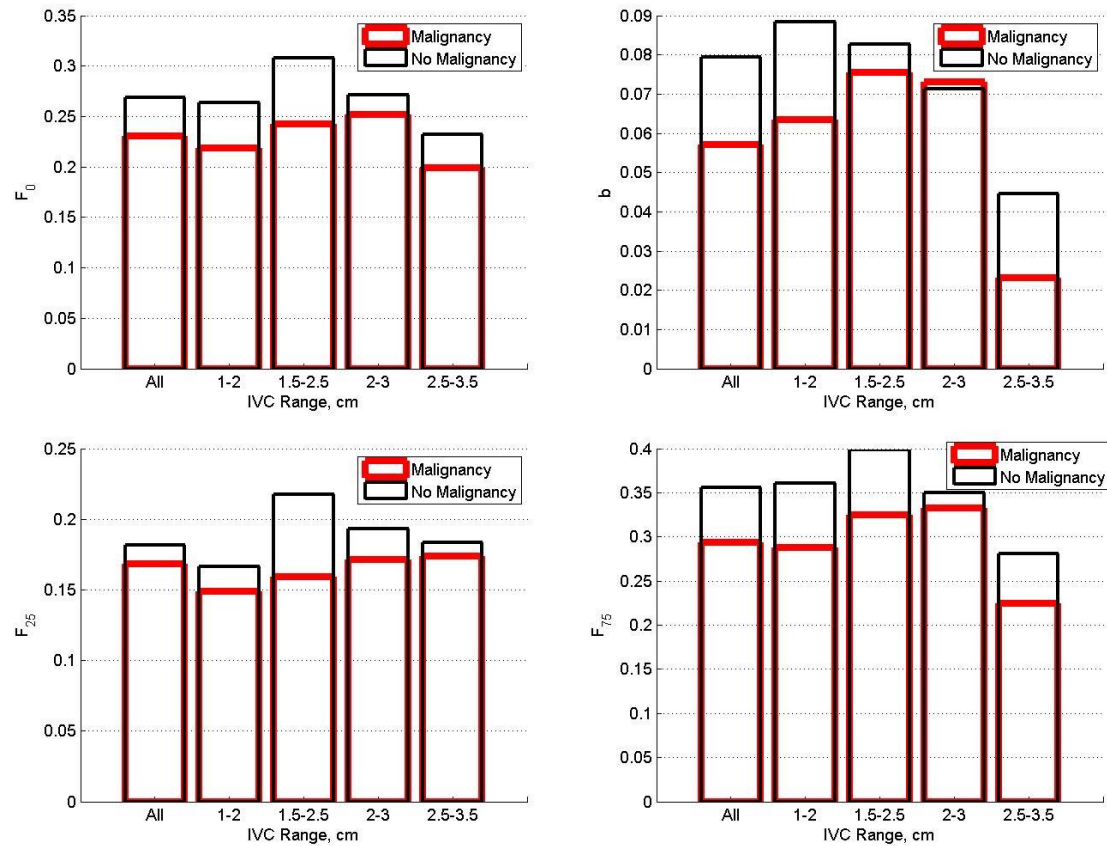


Figure 32: Sigmoidal fit values for patients with and without a history of malignancy with different IVC diameter ranges

These results may indicate that the effect of malignancy is prevalent in patients with an IVC diameter at or below the normal range. This suggestion was supported when including the forces that did not cause perforation, as shown in the below figure. At a lower IVC diameter, a higher

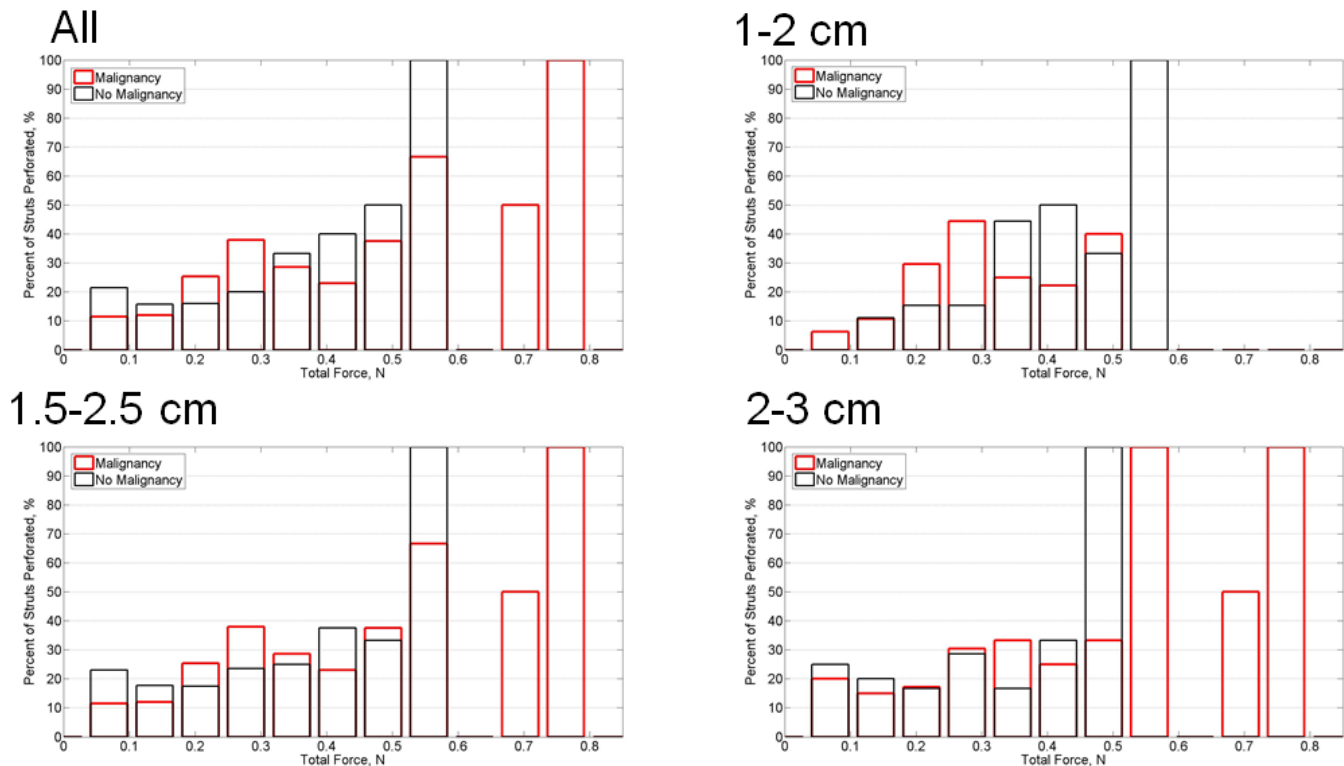


Figure 33: Percentage of struts that perforated in a given force range and IVC diameter range for patients with and without a history of malignancy

percentage of struts perforated for patients with a history of malignancy. As the IVC diameter was increased, this difference decreased, similar to the trend found between female and male patients.

To observe the overall effect of the IVC diameter, all 37 patients were plotted while applying ranges for IVC diameter prior to perforation. This is shown below. It can be seen that

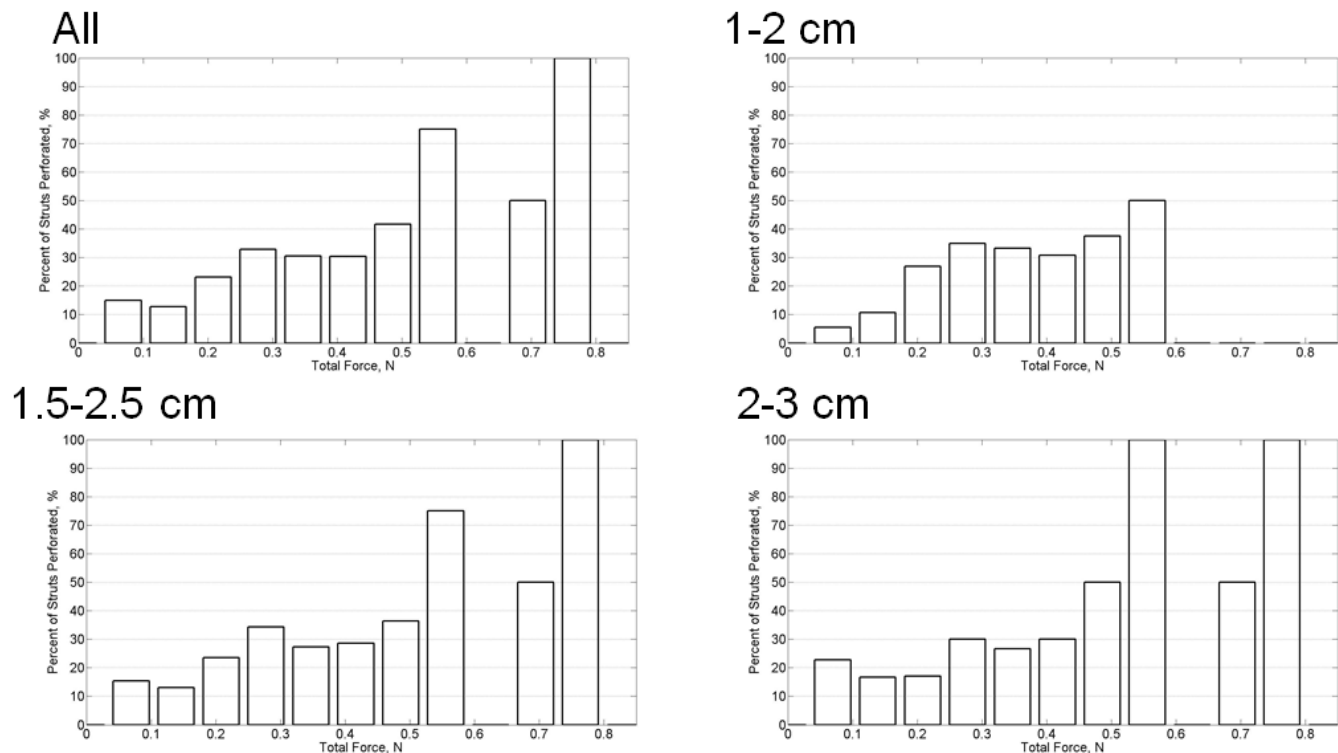


Figure 34: Percentage of struts that perforated in a given force range and IVC diameter range for all patients

at lower IVC diameters prior to a given perforation, a specific force may be more likely to perforate in comparison to in a larger IVC diameter.

After separately observing the effects of days between CT studies and IVC diameter on the forces that result in perforation, plots were created that combined the two different ranges. It was again found that eliminating data of CT studies less than 50 days showed no difference in the plots.

4.2.6 Progressive Perforation

After studying the impact of days between CT studies and of IVC diameter, the effect of progressive perforation, or additional perforation that occurs after an initial perforation, was

observed. This is noticed in the below plot of forces that resulted in perforation categorized based on existing strut perforation. As can be seen, perforations occurred at significantly lower

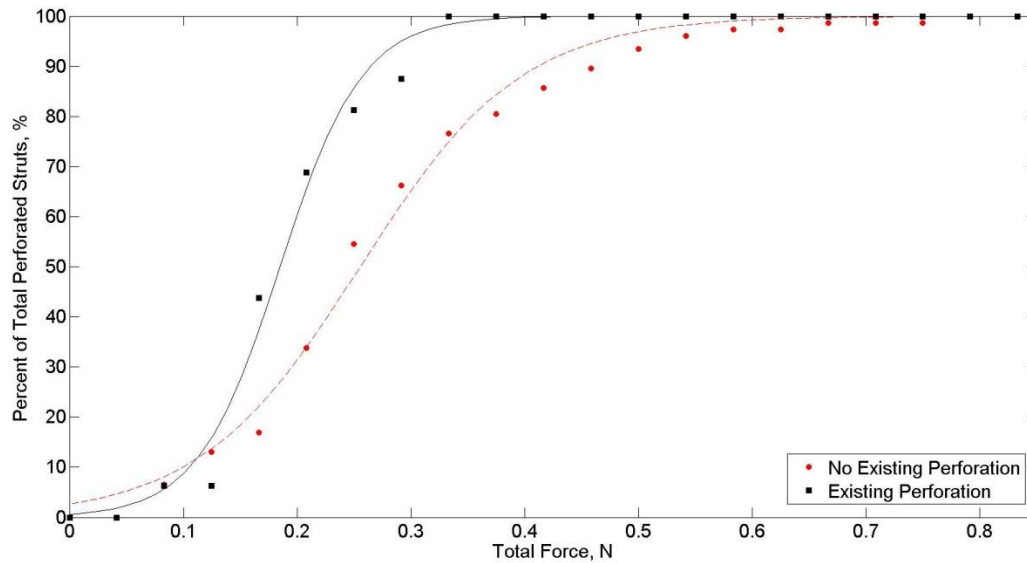


Figure 35: Forces that caused perforation dependent on if there was existing strut perforation(s) in the patient

forces if there was an existing perforation. The mean difference of these two groups is shown below, indicating a significant difference ($p = 0.0193$).

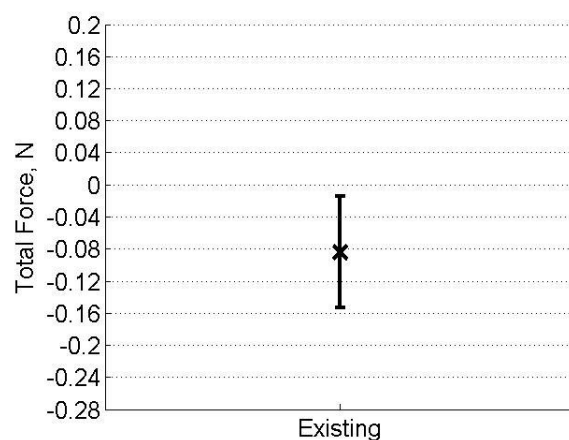


Figure 36: Mean difference in forces that caused perforation dependent on if there was existing strut perforation(s) in the patient

Additionally, the sigmoid fit values are shown below in Figure 37, indicating the large difference based on the presence of a perforation.

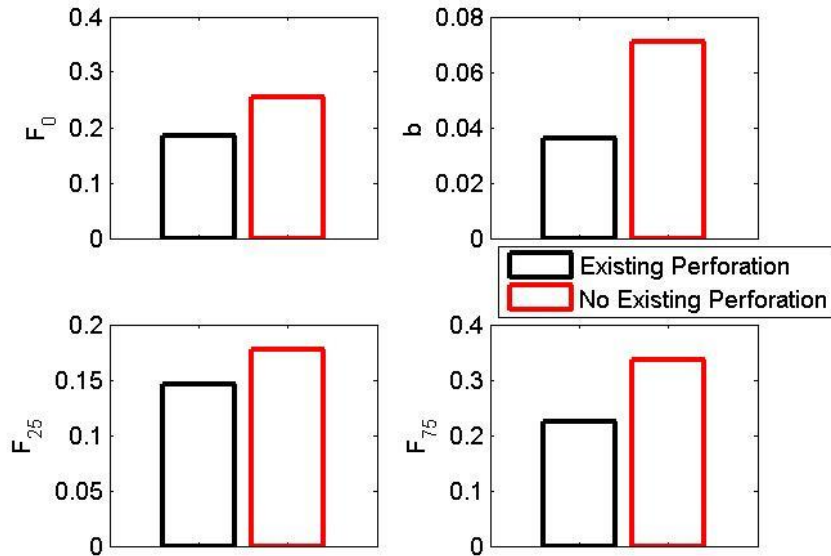


Figure 37: Sigmoidal fit values for perforations occurring based on existing perforation

However, when removing forces for perforations that occurred following a previous perforation, the difference between patient groups did not vary from what has been previously discussed. It should be noted, however, that all curves were shifted to the right, as expected based on the plot in Figure 35. This may suggest that effects of patient gender and history of malignancy are consistent with and without existing filter strut perforations. Lastly, it was observed that all plots using the average total force on the strut face would remain consistent if the average normal force had been used.

5. Discussion

With safety concerns arising from the long-term use of retrievable IVCs, a goal of this study was to assist in the development of follow-up procedures to prevent unnecessary retrieval complications. This study investigated whether the employment of finite element modeling, in conjunction with CT studies, can aid in revealing the risk of strut perforation in patients. Additionally, it aimed to reveal reasoning for the previously observed difference in perforation rates among male and female patients and between patients with and without a history of malignancy.

Results of filter simulations in this study indicate that strut perforation is more likely to occur at higher average total and normal forces. These forces change over time based on the displacement of the filter strut faces, dictated by the shape of the IVC. Additionally, application of models to follow-up CT studies was able to identify struts that may be at-risk for perforation. By indicating struts at-risk of perforation, complicated retrievals may be prevented by suggesting filter retrieval before initial or additional strut perforation occurs. Furthermore, the risk of a strut with a given average total or normal force value may be more accurately determined by including patient gender and history of malignancy, as observed in the previous study [10]. Additionally, the number of days between CT studies may have an impact as to whether a force results in perforation, as indicated by significantly less perforations occurring for CT studies less than 50 days apart, independent of force.

When examining the patient groups based on gender and malignancy history, the study results indicate that the size of the IVC diameter may factor into the significance of the patient's gender and history of malignancy in determining the forces that are likely to perforate. More specifically, a larger diameter appeared to increase the difference between forces that result in

perforation for female and male patients. However, when including forces that did not result in perforation, a lower diameter indicated female patients were more susceptible to perforations. When looking at the effect malignancy, a smaller IVC diameter appeared to decrease the forces that cause perforation and increase the likelihood of perforation in patients with a history of malignancy.

The significant difference at lower IVC diameters, specifically 1 to 2 cm, among patients sorted by malignancy history suggests that patients with a history of malignancy have a weaker IVC wall or another difference that allows perforation. This change in properties and increase in perforation rate may be a result of chemotherapy or other effects from a cancer patient in comparison to patients without a history of malignancy. Moreover, a lower IVC diameter is expected to increase filter deformation, therefore increasing the average total and normal forces observed on the strut faces. Furthermore, it was observed that an existing perforation allows additional perforations to occur at lower forces while decreasing the IVC diameter. These results support the idea that perforation is more likely to occur in IVCs of lower diameters. This effect at lower diameters, in combination with an IVC wall more susceptible to perforation, may highlight the increased risk of perforation in patients with a history of malignancy. However, at larger IVC diameters it was observed that perforation forces in patients without a history of malignancy were larger than patients with a history of malignancy. Despite this perforation difference, the percentage of struts that perforated at larger IVC diameters was similar.

In female and male patients, the two different plots contradicted when investigating the effect of IVC diameter prior to perforation. Perforation forces in female patients in large IVC diameters were significantly lower than in male patients. However, a higher percentage of struts perforated in female patients at smaller IVC diameters. Further analysis may be required to better

understand these differing results. The reasoning for these results for patient gender is unknown, but may be a result of the difference in atherosclerosis among female and male patients [16, 17].

As mentioned previously, it was concluded that existing strut perforation in a patient allows for additional perforations to occur at significantly lower forces. Removing this effect from the patient groups based on gender and malignancy history resulted in no change relative to each other. This indicates that existing perforation allows perforations to occur at lower forces independent of IVC wall properties before an initial perforation.

This study has limitations, but the process of applying a model to simulate filters based on follow-up CT studies can be repeated for other filter designs to assess the risk of strut perforation. However, the available CT studies in this study limited the analysis of forces that cause perforation, particularly due to a large range and an inconsistent number of days between CT studies. A larger number of days between CT studies may allow forces to increase or decrease on a filter strut while a smaller number of days may not allow strut perforation to be observed. Additionally, only filter strut face displacements relative to the center of the filter were included in the filter simulations.

Therefore, in future work, additional factors will be included in the simulation, such as blood flow, blood pressure, and clots contained by the filter. This is expected to provide a more accurate model and may improve the distinction between female and male patients, and between patients with and without a history of malignancy. Additionally, a similar study will be applied to the Greenfield IVCF, which has indicated a lower perforation rate in comparison to the studied Celect IVCF. The resulting comparison of the two filters will provide a more comprehensive view of forces and mechanical aspects involved in perforation.

6. Conclusion

In conclusion, the study's findings indicate that CT follow-up, in combination with model simulations, can assess the risk of strut perforation in a patient. The risk associated with a given force value may be dependent on patient gender, history of malignancy, and IVC diameter. By identifying perforation risks, conditions resulting in complicated IVCF retrievals may be prevented.

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Appendix A: Results

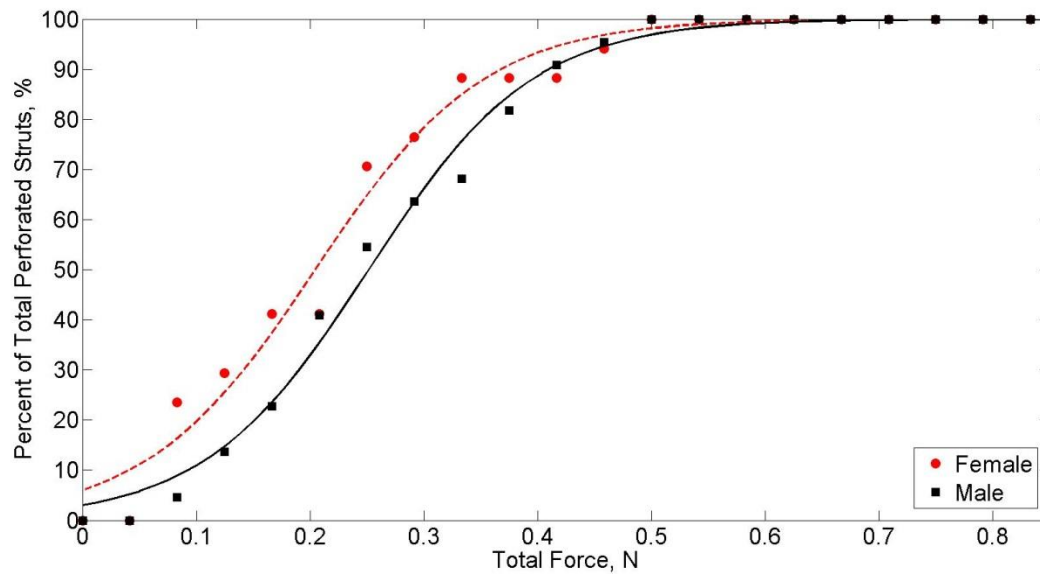


Figure A1: Female and male patients with an IVC diameter at filter placement between 1 and 2 cm

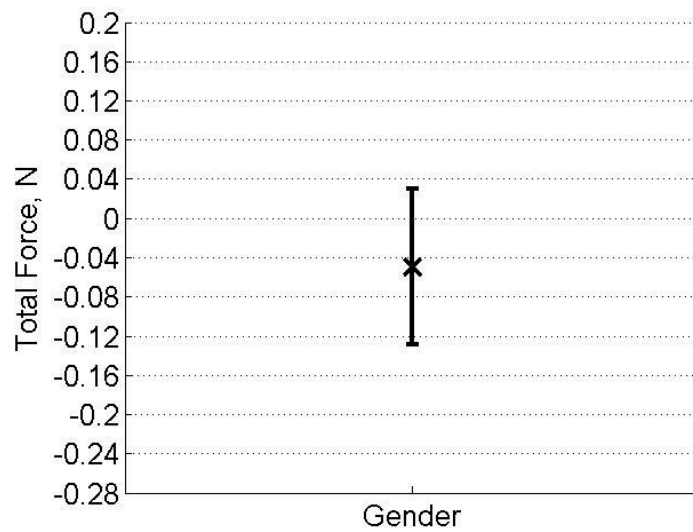


Figure A2: Mean difference for female and male patients with an IVC diameter at filter placement between 1 and 2 cm ($p = 0.2147$)

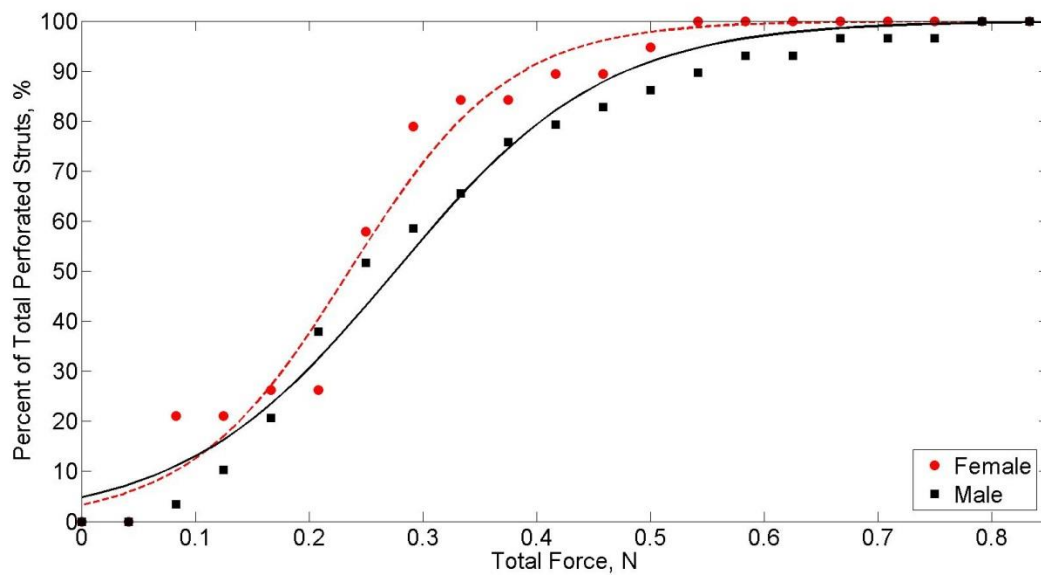


Figure A3: Female and male patients with an IVC diameter at filter placement between 1.5 and 2.5 cm

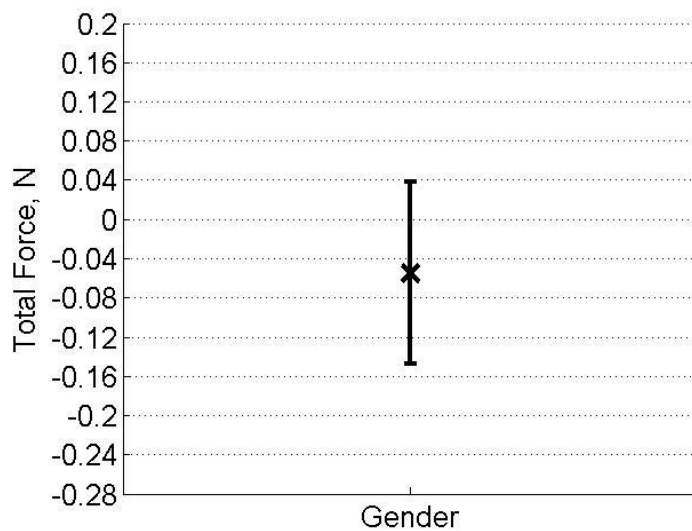


Figure A4: Mean difference for female and male patients with an IVC diameter at filter placement between 1.5 and 2.5 cm ($p = 0.2436$)

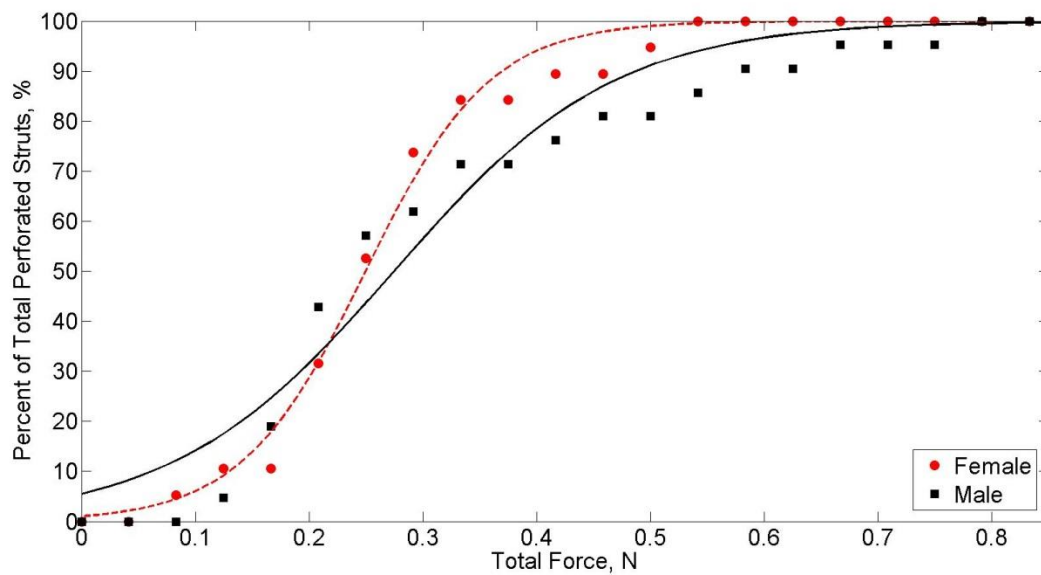


Figure A5: Female and male patients with an IVC diameter at filter placement between 2 and 3 cm

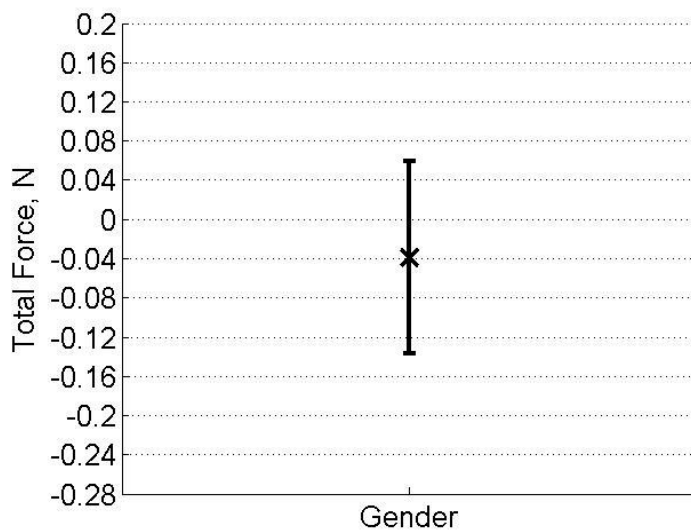


Figure A6: Mean difference for female and male patients with an IVC diameter at filter placement between 2 and 3 cm ($p = 0.4288$)

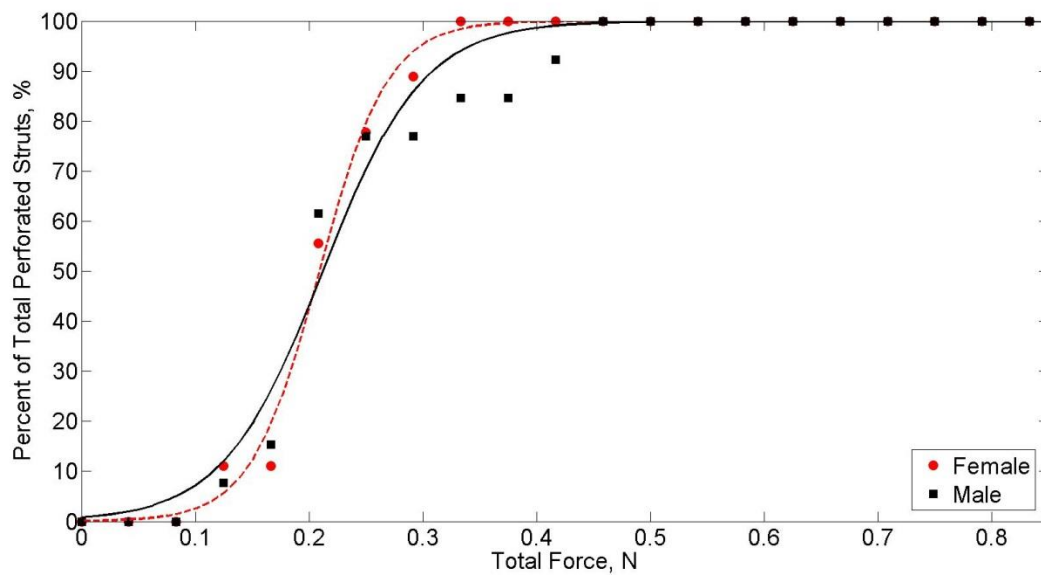


Figure A7: Female and male patients with an IVC diameter at filter placement between 2.5 and 3.5 cm

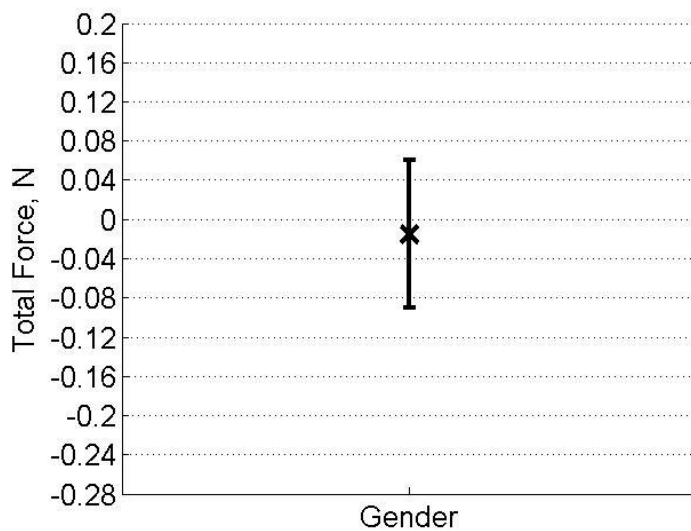


Figure A8: Mean difference for female and male patients with an IVC diameter at filter placement between 2.5 and 3.5 cm ($p = 0.6853$)

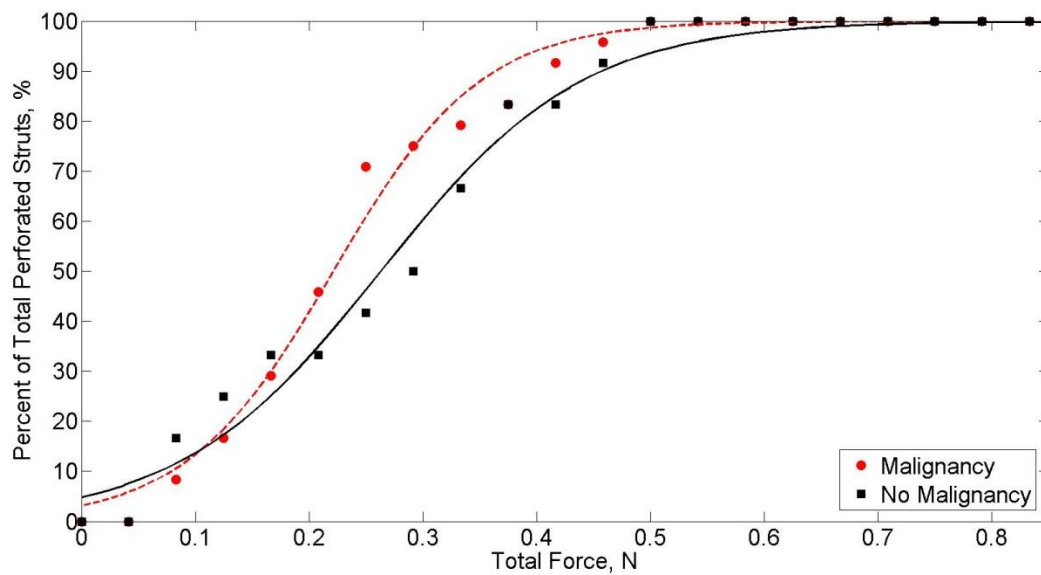


Figure A9: History of malignancy grouped patients with an IVC diameter at filter placement between 1 and 2 cm

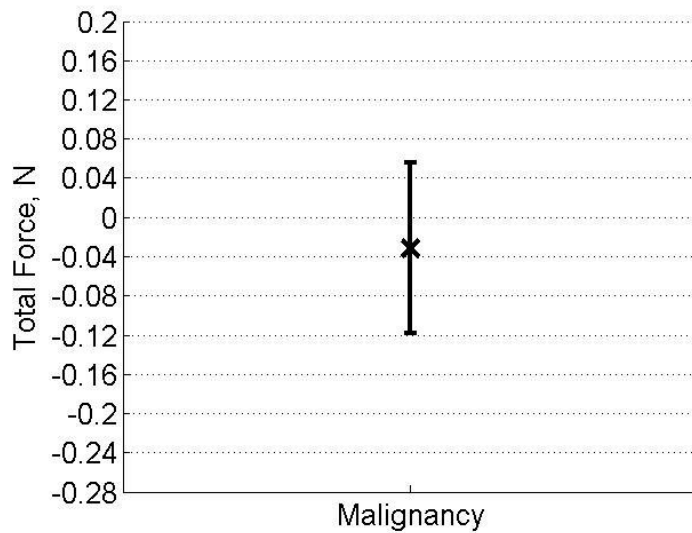


Figure A10: Mean difference for history of malignancy grouped patients with an IVC diameter at filter placement between 1 and 2 cm ($p = 0.4665$)

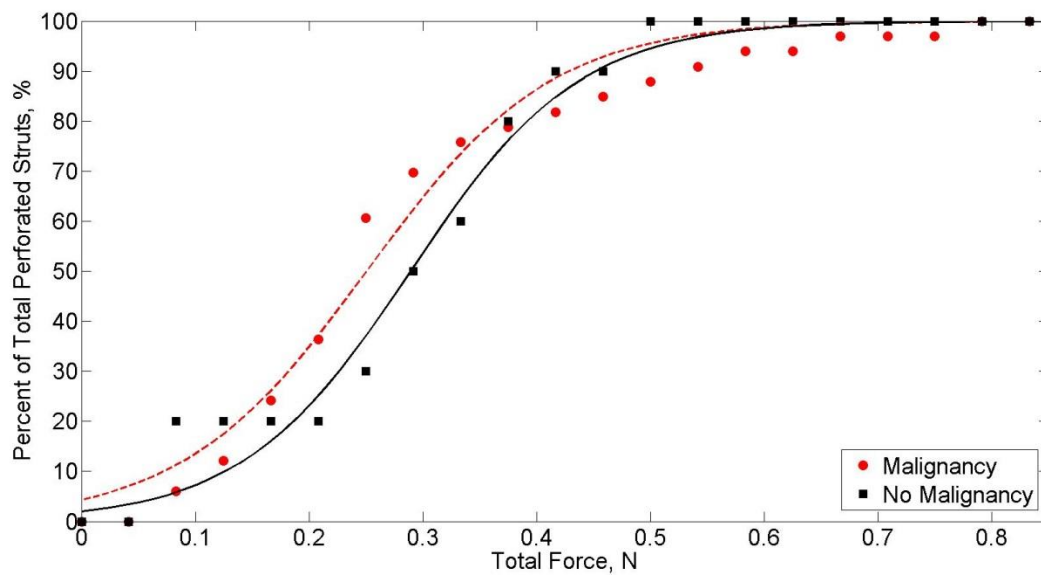


Figure A11: History of malignancy grouped patients with an IVC diameter at filter placement between 1.5 and 2.5 cm

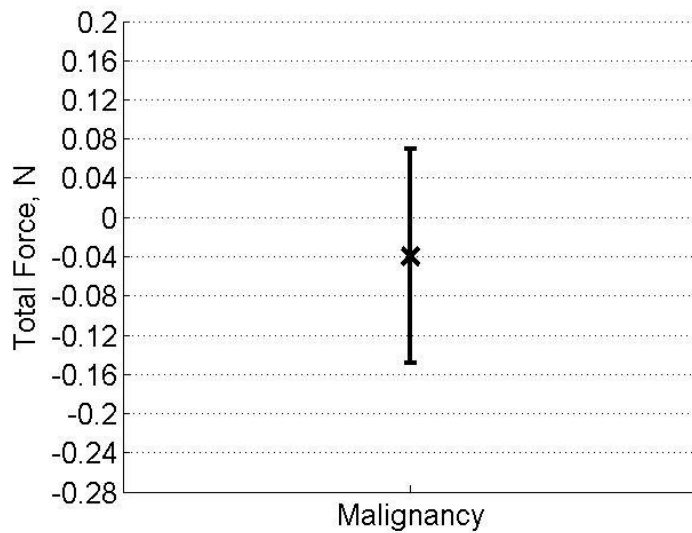


Figure A12: Mean difference for history of malignancy grouped patients with an IVC diameter at filter placement between 1.5 and 2.5 cm ($p = 0.4680$)

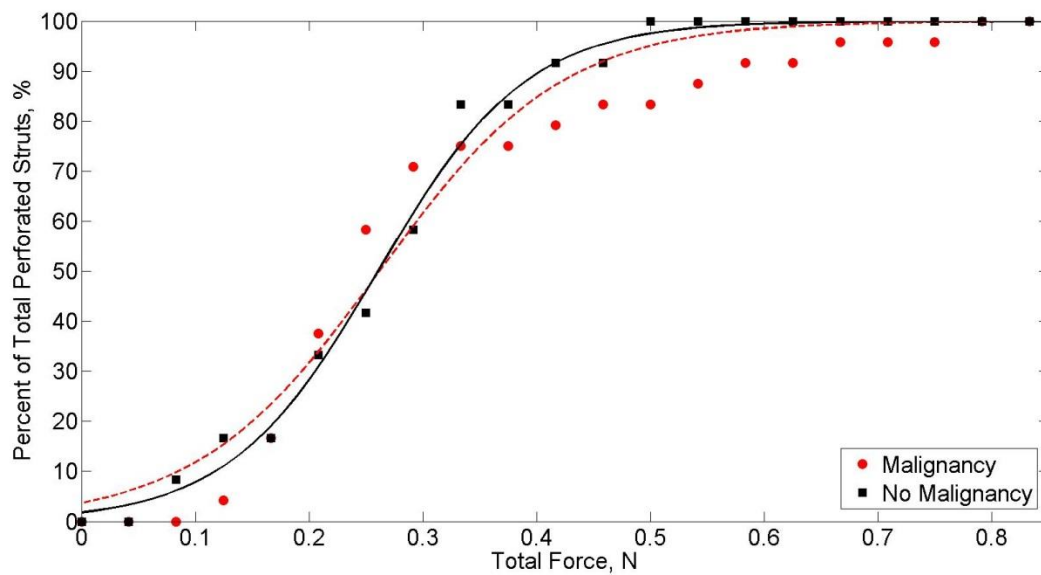


Figure A13: History of malignancy grouped patients with an IVC diameter at filter placement between 2 and 3 cm

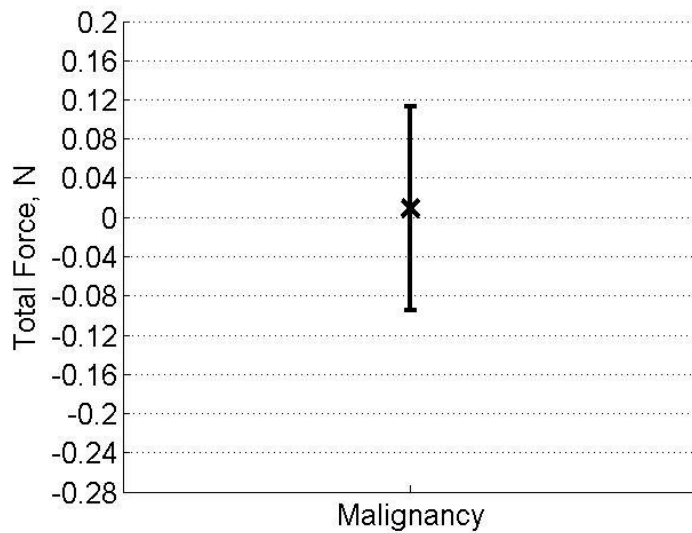


Figure A14: Mean difference for history of malignancy grouped patients with an IVC diameter at filter placement between 2 and 3 cm ($p = 0.8590$)

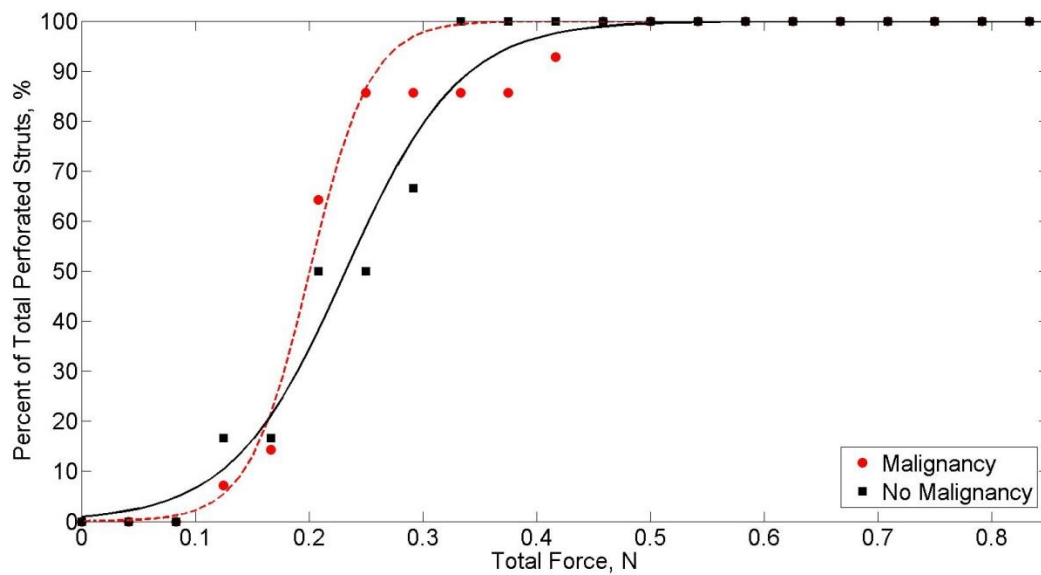


Figure A15: History of malignancy grouped patients with an IVC diameter at filter placement between 2.5 and 3.5 cm

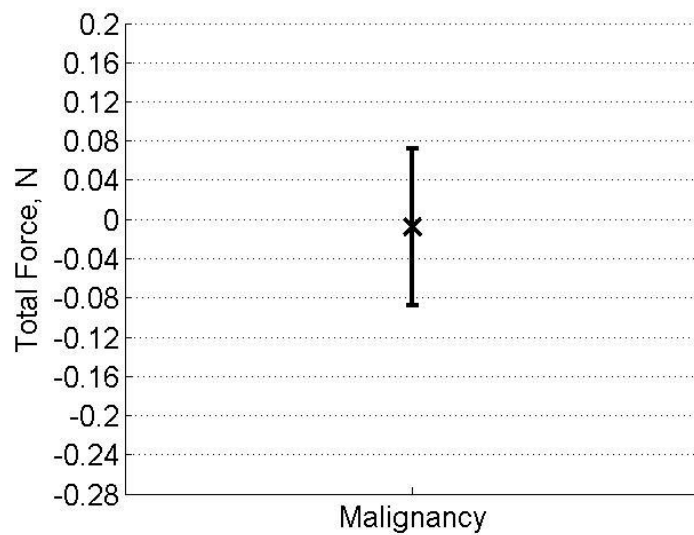


Figure A16: Mean difference for history of malignancy grouped patients with an IVC diameter at filter placement between 2.5 and 3.5 cm ($p = 0.8431$)

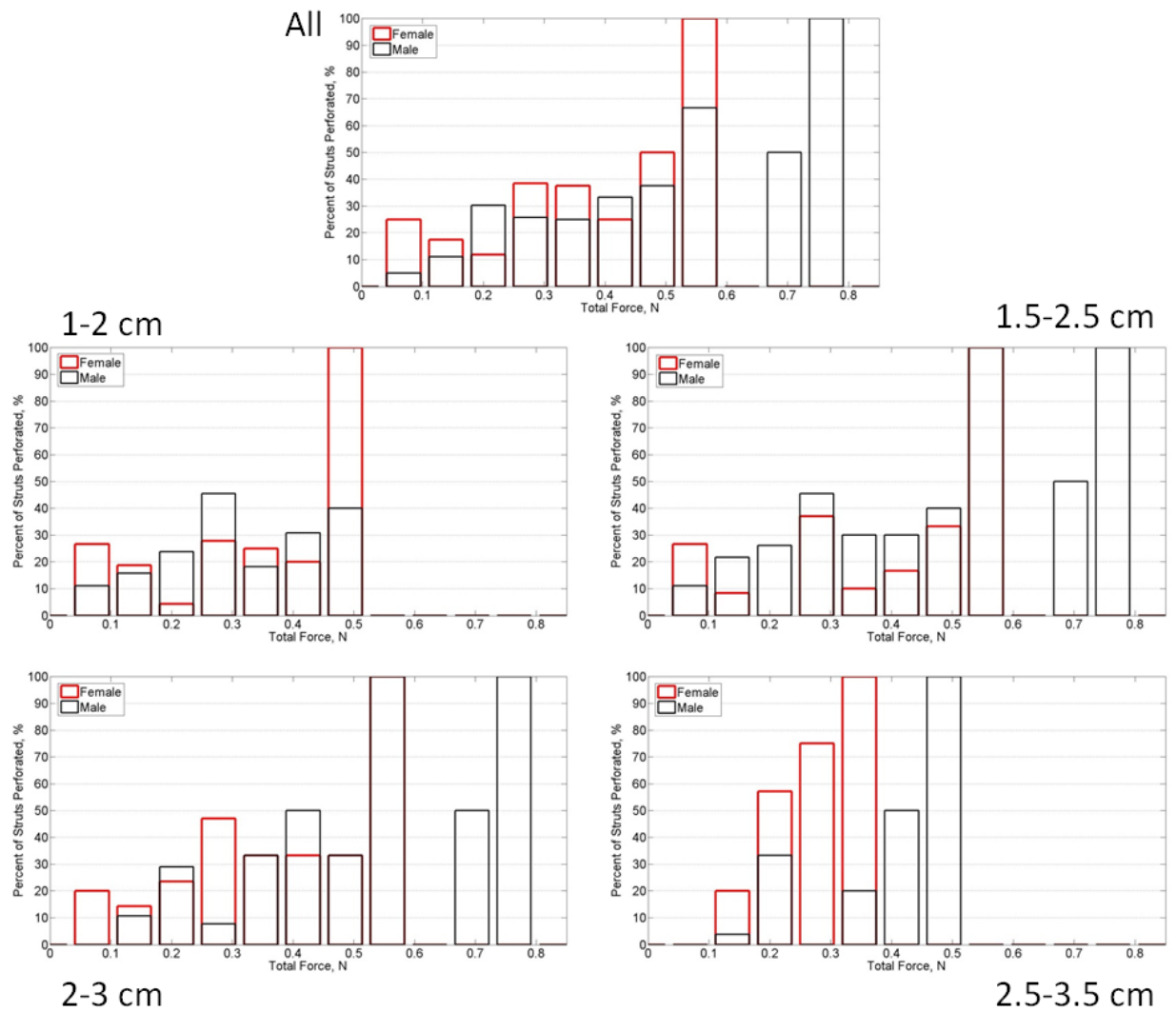


Figure A17: Percentage of struts perforated in specified force ranges for female and male patients with different IVC diameters at filter placement

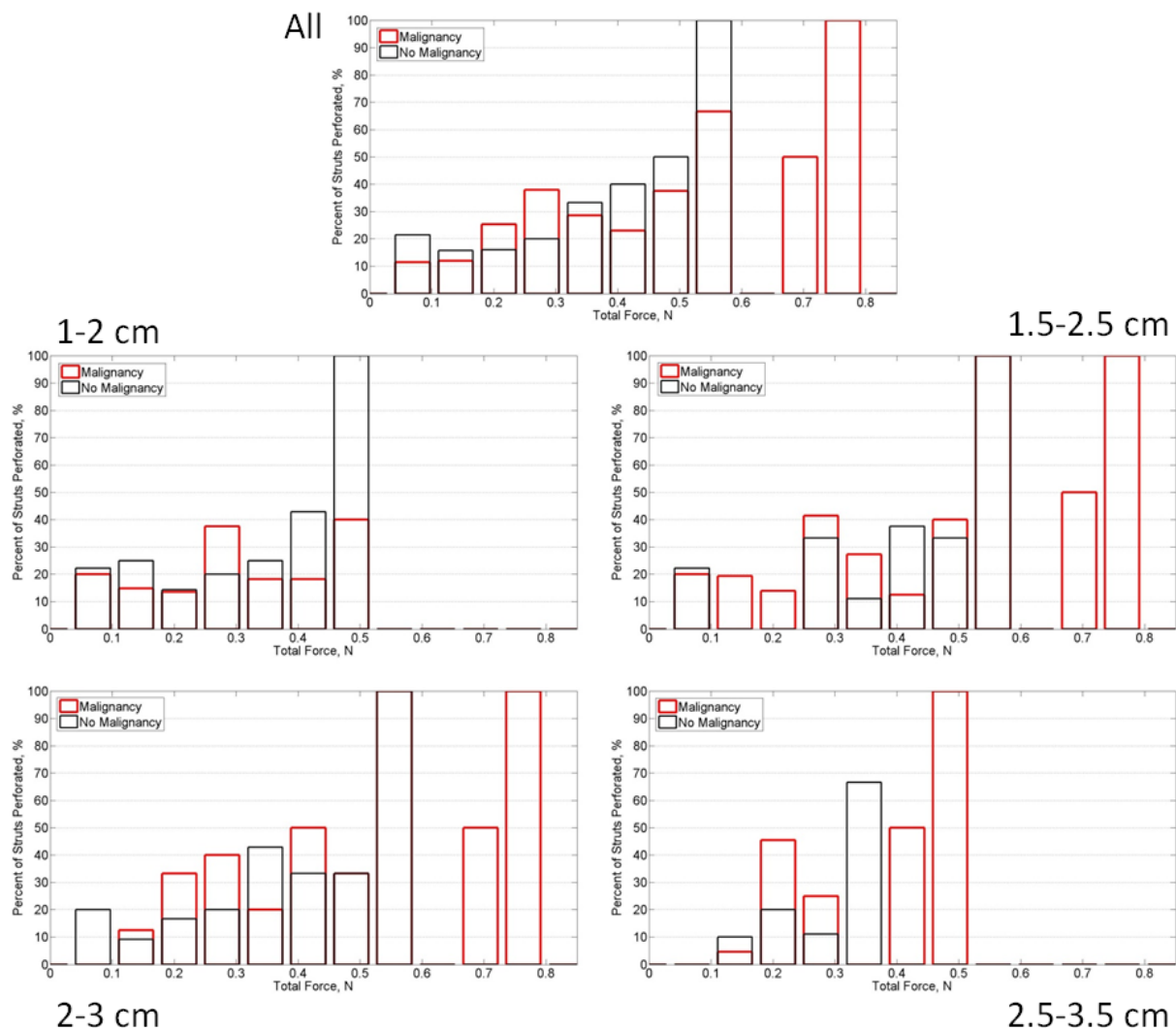


Figure A18: Percentage of struts perforated in specified force ranges for history of malignancy grouped patients with different IVC diameters at filter placement

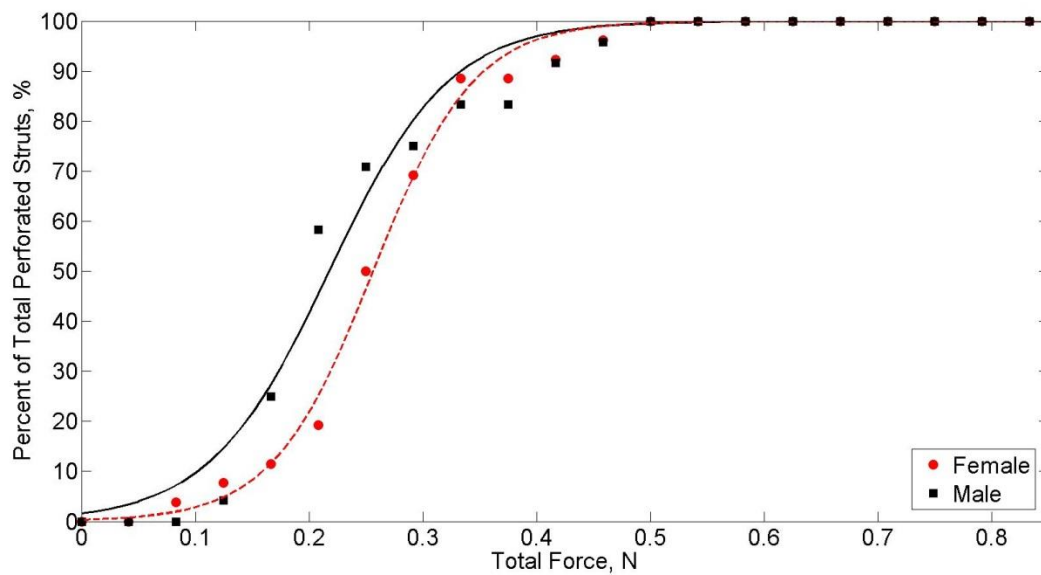


Figure A19: Female and male patients with an IVC diameter prior to a perforation between 1 and 2 cm

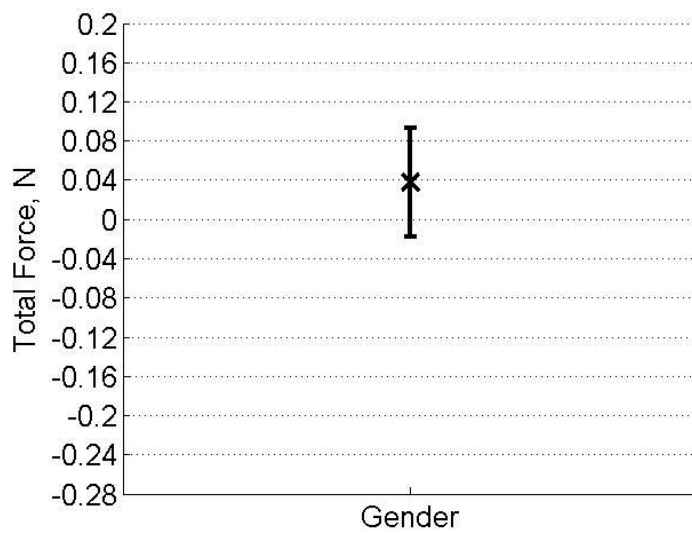


Figure A20: Mean difference for female and male patients with an IVC diameter prior to a perforation between 1 and 2 cm ($p = 0.1754$)

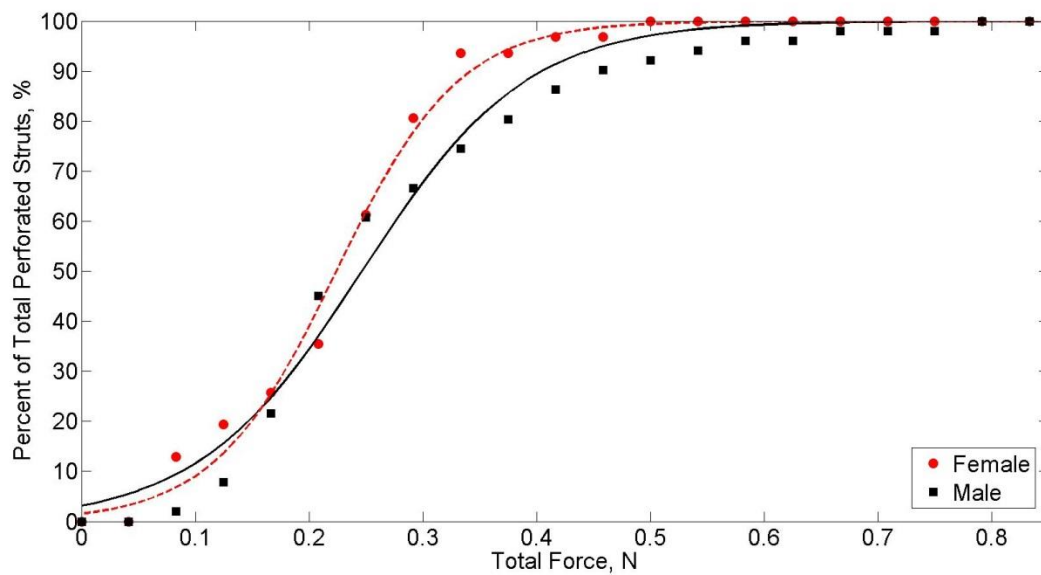


Figure A21: Female and male patients with an IVC diameter prior to a perforation between 1.5 and 2.5 cm

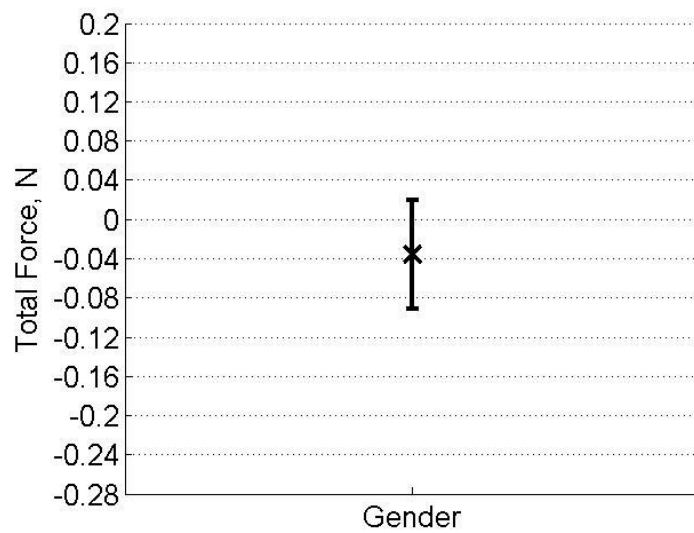


Figure A22: Mean difference for female and male patients with an IVC diameter prior to a perforation between 1.5 and 2.5 cm ($p = 0.2063$)

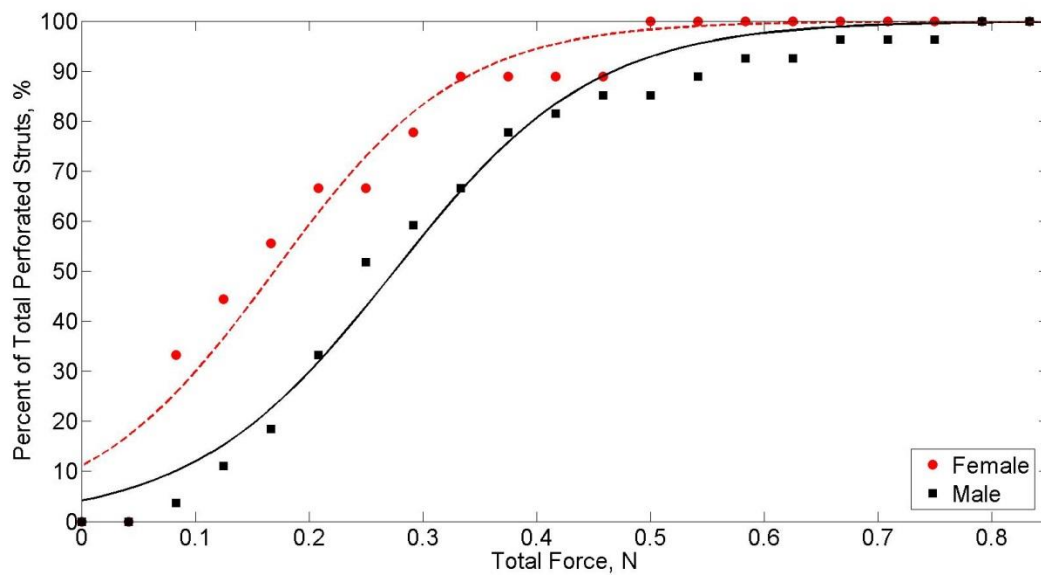


Figure A23: Female and male patients with an IVC diameter prior to a perforation between 2 and 3 cm

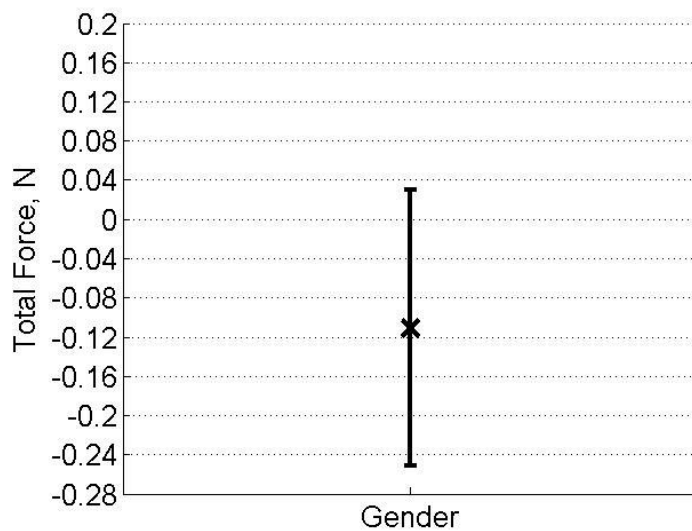


Figure A24: Mean difference for female and male patients with an IVC diameter prior to a perforation between 2 and 3 cm ($p = 0.0506$)

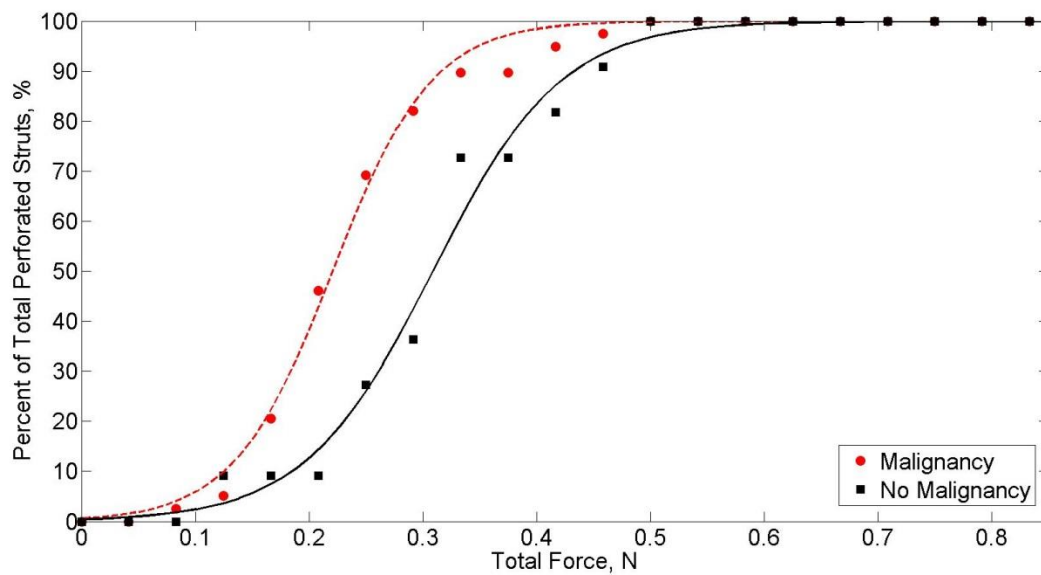


Figure A25: History of malignancy grouped patients with an IVC diameter prior to a perforation between 1 and 2 cm

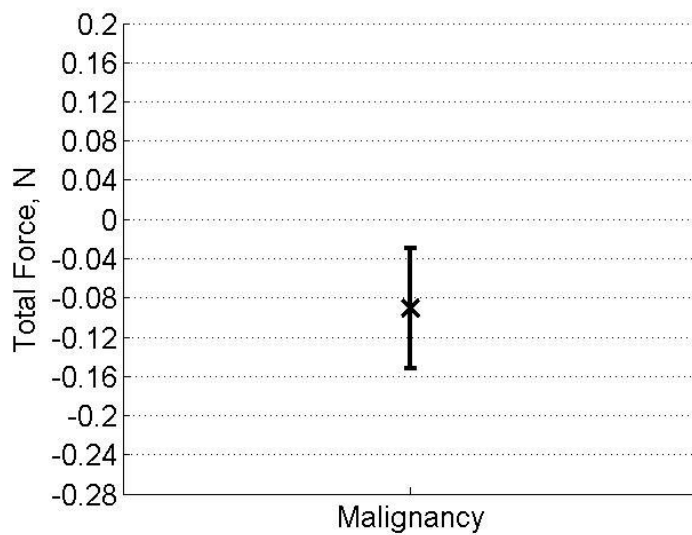


Figure A26: Mean difference for history of malignancy grouped patients with an IVC diameter prior to a perforation between 1 and 2 cm ($p = 0.0044$)

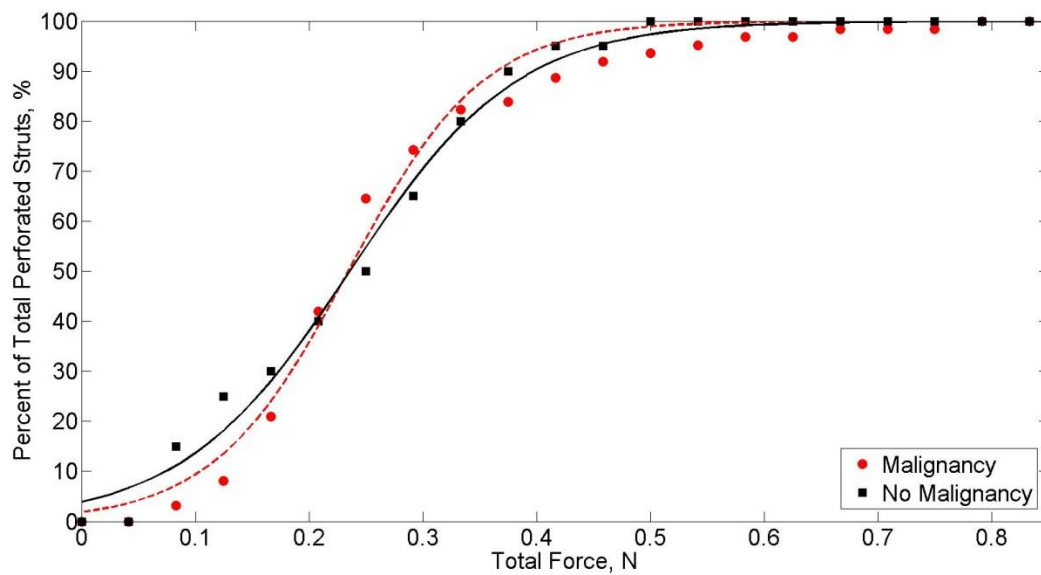


Figure A27: History of malignancy grouped patients with an IVC diameter prior to a perforation between 1.5 and 2.5 cm

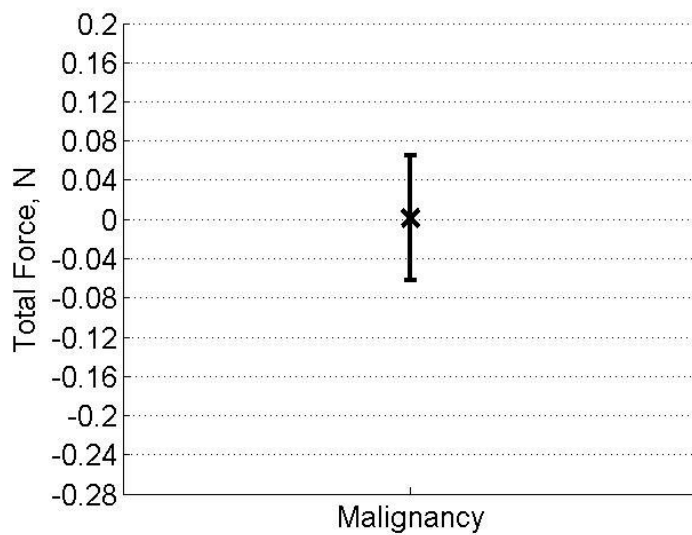


Figure A28: Mean difference for history of malignancy grouped patients with an IVC diameter prior to a perforation between 1.5 and 2.5 cm ($p = 0.4623$)

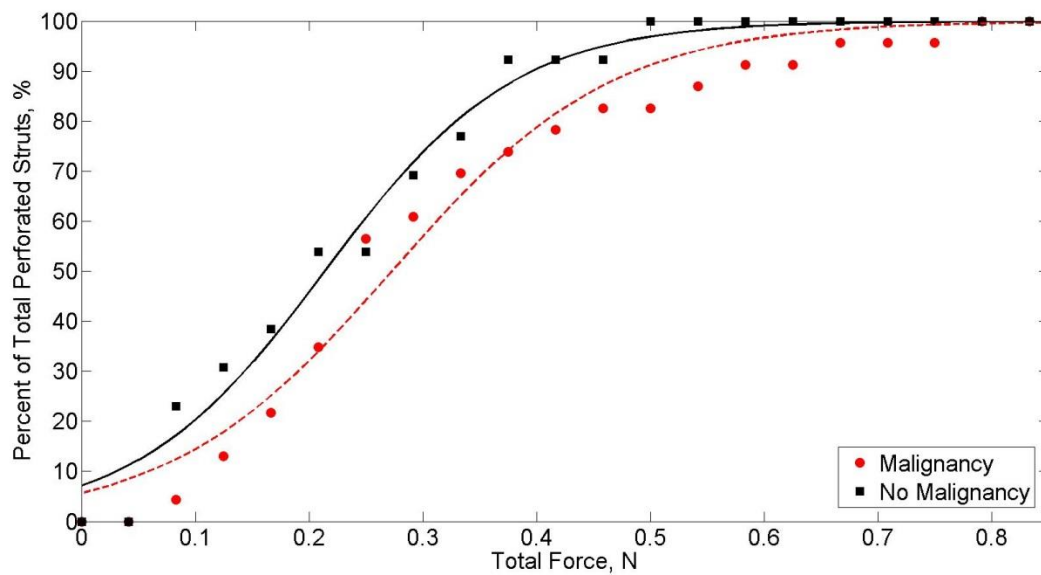


Figure A29: History of malignancy grouped patients with an IVC diameter prior to a perforation between 2 and 3 cm

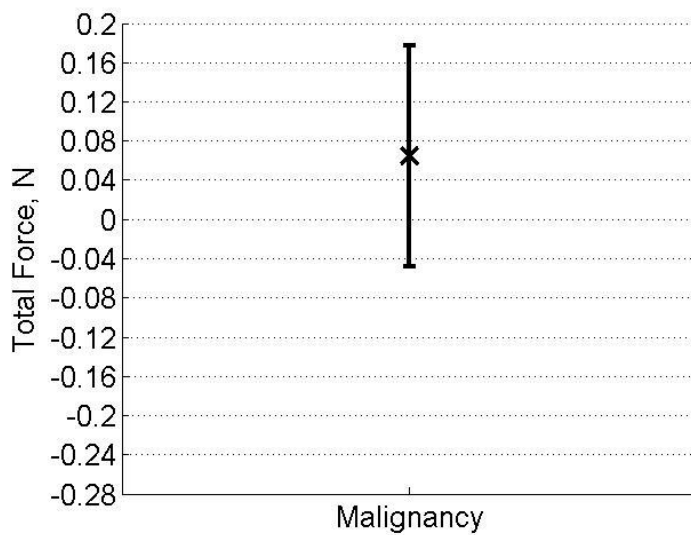


Figure A30: Mean difference for history of malignancy grouped patients with an IVC diameter prior to a perforation between 2 and 3 cm ($p = 0.2511$)